Implementing innovation more effectively within the highly regulated non-invasive medical device field: a case of Pragmatic Entrepreneurship

A context statement submitted to Middlesex University in partial fulfilment of the requirements for the degree of Doctor of Professional Studies

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1. Acknowledgements

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2. Introduction and Personal Perspective

My public works are a combination of a number of varied examples that when combined demonstrate that during my 26 year career I have not only contributed to but have significantly affected daily practice by implementing innovation more effectively within the non-invasive medical devices field. In the following sections I will reflect on these public works and in context outline how through both institutional and work based learning I gained and imparted new knowledge to my field of expertise. I will explore the barriers to successful implementation of innovation and will elaborate on the specific challenges faced as I transitioned within, and between organizations and up the leadership ladder. I will explore how I overcame these varied challenges and created new opportunities along the way implementing a number of innovative products into the global marketplace. I will demonstrate how I established and managed innovative organizations with virtual structured teams of uniquely competent professionals across dispersed geographic locations, encompassing the required expertise in all the highly technical and clinical areas needed to allow for more effective implementation of complex medical products. I will then expand this discussion further to evidence my more effective implementation of a number of innovations. Furthermore, I will illustrate my progression and provide examples of my journey to becoming a pragmatic entrepreneur. I will conclude by detailing and critiquing my unique contribution to the field, supporting my claim that I have; *'Implemented innovation more effectively within the highly regulated non-invasive medical device field'.*

2.1. My early background

From as early as comprehensive school I've had a keen realization that I needed to broaden my knowledge base in order to be successful in life. Coming from a poor working-class family as the middle child of seven, it was clearly evident that in order to make a success of my life that I would need to forge my own path. After completing school I entered the work pool and spent the next six months as a manual labourer on one of the local nurseries in West Sussex. I recall starting my days at four in the morning in the freezing cold harvesting lettuce for market with a knife. Although manual labour was nothing new to me, the harshness of this endeavour for the measly returns I would earn was one of my first examples of on-the-job learning. I learnt during this time that; hard physical work was nothing to be ashamed of, that comradeship and a positive attitude made the work seem easier, and most importantly, that clearly this was not the career path I wanted to pursue long-term. Consequentially, I went back to technical college to study for an Ordinary National Diploma in engineering.

I re-entered the workforce in 1986 and was employed initially as a service engineer at the European headquarters of an American medical device conglomerate focused in the respiratory and ventilator fields based in London, and became immersed in learning my new trade. This workplace learning involved hands-on instruction, such that you might expect in a traditional apprenticeship, combined with a significant amount of classroom learning taught by my manager. As part of company structured education I was also sent to attend in-depth product related training at the company's factories in the United States. These early trips went a long way in solidifying my career path, as not only did I realize that I had a yearning to learn as much as possible about this exciting field, but I also came to appreciate the importance of gaining different perspectives from around the world. During this period I also took advantage of the company-sponsored continuing education program and completed a Higher National Certificate in Engineering. After earning the respect of my peers by my hard work and an insatiable appetite to be involved, I was given the opportunity of taking over the technical education responsibilities for European operations of the company. These were my first evolutionary steps as an educator. I fondly look back at these early days, as this is when I started to appreciate the importance of continued learning and also honed my presentation and teaching skills. My time was now increasingly spent furthering my knowledge about the respiratory and ventilator field, the technical and clinical aspects of the company's current and new products, and then assimilating this new knowledge into various training courses which usually were between 3 to 5 days in duration. This involved drafting pre-study material (Griffiths & Canfield, 1993)[1] that brought all students up to the same starting point prior to attending my classes, as well as developing detailed training manuals that involved both classroom learning and hands-on workshops. The majority of my classes were evaluated by the students with effectiveness matrices being kept to provide input into content and for delivery improvement. The classes also involved assessment of the student's learning by daily tests and final examination that included many practical hands-on elements. I found that many of the teaching approaches I had encountered could be improved upon in order to gain greater knowledge transfer and enjoyment of the learning process for both the students and teacher alike. I think this interdisciplinary co-dependency was aptly described early on by Dr. Karl Rosenkranz in his book Pedagogics as a System (1872, p. 5) when he states "it (the art of teaching) is rather a mixed science which has its presuppositions in many others. In this respect it resembles medicine." An interrelationship that is particularly poignant in my particular instance.

[1] These pre-study booklets are still being used in predominantly the same form today by the company as the core physiological and mechanical ventilator concepts and science is the same.

Over the next four years, I refined my craft and taught classes to hundreds of learners from across the globe, sometimes at offices in London but in many cases internationally. I frequently travelled and conducted well over one hundred technical and clinical seminars on every continent. As a young professional this was incredibly exciting and provided me with a strong grounding in not just the core competences of my profession, but equally importantly, in the varied cultures and approaches to healthcare from across the globe. I found that the thirst for knowledge and desire to do a good job was universal. Even if the political and environmental situations did everything to discourage such ideals. I recall one specific incident that brought this point home. On my first visit to Moscow in 1986, when things were still well under the Soviet era regime, I was lecturing at the Bakoulev Cardiac Institute (2012), utilizing a presentation that I had used many timed before which was on a specific form of ventilation which required utilizing aggressive hemodynamic support from a type of drug called vasopressors.[2] Suddenly, a young bearded Russian physician stood up and said in broken English "this is all very interesting, but we have no access to such drugs in Russia, so how can we apply such approaches?" This made the main conclusion of my talk somewhat futile and required me to address the issue with a whole different clinical regimen based around the resources they did posses, namely; good old hands on bedside skills and strong physiological knowledge, something that has been lost to some degree in the western world with our reliance on technology and drugs. I leant a number of valuable lessons that day; one being the importance of researching and adapting your material to the audience, another the disparity in healthcare services from one country to another, and most importantly the need to ethically develop medical devices that can be utilized as broadly as possible in the less developed countries. Ethics is critical not only in day to day business dealings, but equally so in our approach to address the enormous healthcare problems we face and will be vital if we are to overcome the great economic and access to care divides that exist globally (Schor, et al., 2011).I will explore this concept of healthcare business ethics further in chapter 4 that details my public works related to the innovations that I have implemented.

To broaden my formal educational background, which to this point had all been in engineering, I decided to undertake a management qualification and attended evening classes to complete my postgraduate Diploma in Management Studies. This decision was driven by my desire to further work my way up the corporate ladder and an interest to broaden my scope of expertise into other areas within the medical device field. However, I recall being concerned at the time about breaking through the 'Glass

[2] Hemodynamic regulation is critically important when trying to mange an acute lung injury patient in acute respiratory distress syndrome with a lung protective ventilator regimen. (J. Zhang, 2011)

Ceiling', related to my trade school working-class background. Probably more precisely referred to as the "old boys' network as expounded on at the time by Jones and Lewis (1998) and that was clearly still in play in British society. Although the company I worked for was American and you would believe was less affected by such stereotypes, there was certainly a pecking order for promotions and career advancement within the British led arm of the organization. Therefore, to progress and succeed, I felt I would need to broaden my horizons. My proposition at the time was simple and twofold; 1) that there would be greater opportunities and hopefully rewards outside of the purely engineering and educational arenas where I had spent the earlier part of my career, and 2) that I had to take full advantage of the unique Anglo-American organization[3] for which I worked. This premise came true in short order, in that both my academic and professional achievements were recognized as I was offered a position as an Education Department Manager based out of the company's newly completed factory in Southern California, USA.

2.2. Expanding my horizons and continued workplace learning

Moving continents was a milestone moment in my career. I would go as far as to say it might be the most important decision I ever made and required me to reflect on not just what I wanted to do, but also on who I wanted to be. From what I had seen and experienced, America was clearly the land of opportunity, less encumbered by the historical restraints that existed within British industry and founded out of adversity for freedom of choice and the right to self-determination. This was a country that I felt championed innovation and cheered for the underdog, where you are applauded for trying and not castigated for failing. Here I hoped I could take my proud British heritage and utilize the knowledge and skills I had learnt to further progress up the career ladder. Once in California I took on responsibility for a broader education department. I spearheaded the development of a number of new training programs and oversaw and participated in the provisions of over thirty week long educational classes each year. I also took advantage of the company's supportive continuing education policy and soon had attended the two week residential professional sales training program by the National Society of Sales Training Executives (NSSTE) which today is known as the Professional Society for Sales & Marketing Training (2012). This course was unique as it was a train the trainer program voluntarily taught by leading sales and marketing training executives from some of the world's leading companies (Procter and Gamble, Wachovia and IBM etc.) and focused on the skills of teaching and developing training

[3] Technically probably more accurately referred to as an American-Anglo organization as it was an American parent company.

material and presentations. By this time that I had come to appreciate that my life did not just happen and that I was responsible as to how it might manifest over time. I also realized that as part of my self-development and acquisition of skills, that it was equally important that I honed my time management, effectiveness and ethical awareness capabilities. To this end I attended the Seven Habits of Highly Effective Leadership weeklong seminar in Utah, hosted by the eminent Stephen R Covey himself. This course taught me not only new skills but introduced me to many concepts that to this day I utilize in daily practice. The structured idea of independence (self-mastery and being true to oneself) combined with interdependence (working together synergistically and ethically towards a win-win) and the awareness of the importance of continued rejuvenation of these principles, is beautiful in its straightforwardness and incredibly relevant in today's increasingly complex business environment (Covey, 1989). Dr. Covey explains it best in discussing his sequel, The 8th Habit - From Effectiveness To Greatness (2004), by saying “In today's challenging and complex world, being highly effective is the price of entry to the playing field. To thrive, innovate, excel, and lead in this new reality, we must reach beyond effectiveness toward fulfilment, contribution, and greatness.” (Covey, 2012). In forthcoming chapters I will elaborate on how I believe I have become more effective in the implementation of innovation within my area of expertise and have attempted to live up to these lofty ideals of fulfilment, contribution, and greatness.

Being based now out of the factory that was responsible for the development and manufacture of all of the company’s intensive care ventilators, I was provided with the unique opportunity to immerse myself in many new facets of the business. I believe that work-based learning can be osmotic as well as through structured programs, a concept characterized by Reinsmith (1997, p. 1) as being a process of unconscious immersion in one's immediate environment. In this manner I was able to absorb new knowledge from my daily discussions with a multitude of colleagues. I attended numerous one-on-one and team meetings with engineers and scientists to discuss the intricacies and function of many new medical devices, which spanned the gamut of intensive care and respiratory segments, as the company was involved in pushing the barriers that had existed previously between such diverse specialties. One project I recall involved a revolutionary continuous fibre-optic intra-arterial blood gas analyzer, that additional to the technological challenges, posed new questions about how to interpret and utilize this previously unavailable real-time data to best affect patient care. More information is not always a good thing if you cannot interpret it in context. In order to gather comparative data from patients with different acute conditions, I spent a number of weeks between the operating theatres and intensive care units of Stanford University Hospital in San Francisco. The new knowledge gained by this project supported the

evolution of new visual models that when published allowed for a graphical shape representation of all the variables in such a way that an “average” clinician might be able to utilize them to impact treatment regimen for their patients. (Adam seiver, 1993) This was literally an eye-opening experience that cemented my interest and desire to explore further the clinical aspects of my chosen field.

By this time my career path had moved away from that of the dedicated educator and became increasingly more interested in the marketing and business aspects of my chosen field. I decided that the next step should be to migrate into product marketing management where I would have direct influence on what products would be developed, how they would be developed and on the sales and marketing strategy to introduce them into the marketplace. Here I spearheaded the development of a number of new products, fostering them through Research and Development (R&D), regulatory approval, into production and then orchestrating their release into the marketplace. By the very nature of these medical device products, I believed it was imperative to broaden my knowledge base to include the perspective of the clinical user. I therefore decided to take evening classes again and enrolled into a clinical degree program in respiratory care, which involved a significant hands-on clinical practicum component. Having worked in the field for over a decade at this time I had a strong understanding of the physiological and technological aspects of respiratory care. However, it was an eye-opener for me having to spend approximately two thousand hours working as a respiratory therapist student at numerous local hospitals. This provided me the opportunity to put myself in someone else's [4] shoes, which is a phrase commonly used to refer to a way of gaining empathic Intelligence (Sherman, 2009), and in this case allowed me to appreciate their perspective. Only by doing this could I truly understand how our life support ventilators directly impact the lives of the patient and caregiver. I found out from clinicians what features and aspects of our devices were liked and gained many insights into improvements we could make. On completing this program I became credentialed as a Certified Respiratory Therapist[5] by the National Board for Respiratory Care (2012). I had also cemented my career move by this time and was initially the Product Marketing Manager, then Senior Product Marketing Manager and ultimately the Group Product Marketing Manager for the organization, with a full department below me. Throughout these positions the knowledge I had gained through formal and informal means across varying areas of specialization was put to work on numerous work projects. From directing my daily practice, to influencing my

[4] the clinician’s

[5] A Respiratory Therapist is a licensed healthcare provider that focuses on the treatment of respiratory problems and the management of ventilator support for such patients, similar to a respiratory nurse specialist in Europe.

interactions with others, to steering new product development and the product development road map, to conducing marketing surveys, to developing sales and marketing materials and programs for our sales executive, and for end user clinicians, to conducting sales and clinical education seminars, to authoring trade related publications. Two specific early example of an educational public work product that had direct impact on the community, and as such are examples of my public works are the Technical (Griffiths, 1996) and Clinical (Griffiths, 1996) Handbooks of Metabolic Monitoring[6]. These publications were made available as educational booklets to any interested parties by the company at no charge and allowed interested academics, and clinicians in the respiratory care field, to educate themselves on the science and importance of non-invasive metabolic monitoring of critically ill patients. An area where traditional predictive equation methods and approaches were shown to be inaccurate, resulting in inadequate nutritional support and exacerbated ventilator consequence (Faisy, et al., 2003). The new knowledge imparted here was of the very highest academic level and covered complex clinical and technological subjects, helping to bring a clear and precise learning to many different professions involved in dealing with these issues in ventilated patients. These publications were an early introduction for me into the rigors of academic research in an involved subject. I learnt extensively how to apply a good methodological approach to these studies and enhanced my ability to provide critical review and analysis of complex subjects. The culmination of this was clear and concise publications that address informatively new knowledge and explain a new state-of-the-art technology. Over a decade later, the knowledge imparted by these booklets is still valid and unique in that no other real-time integrated metabolic monitoring product for ventilated patients has been developed and these metabolic monitoring devices are still in use in numerous institutions throughout the globe; (Reid, 2007) (Faisy, et al., 2003), (Miwa, et al., 2003).etc. These newly learnt abilities and this work result clearly helped me to further my career and formed the basis for my approach to many projects that ultimately helped me to progress further up the corporate ladder within the

[6] Metabolic monitoring traditionally refers to a spot-check measurement of a patient's Oxygen Consumption (VO_2) and Carbon Dioxide production (VCO_2)production, which when divided by each other gives you the Respiratory Quotient (RQ) and can be used to calculate the total Resting Energy Expenditure (REE), which is a measurement of total caloric needs. The problem was these measurement were inherently difficult to obtain and the values taken on a spot check basis did not track true metabolism as the patient's clinical condition varied over time, resulting commonly in dangerous overfeeding, underfeeding and inadequate ventilator support. The unique technology outlined in these booklets provided easy real-time continuous measurements of these previously described parameters, and along with that with an entered urine urea value (representing nitrogen metabolism))the actual breakdown of substrate (Fat, Protein and Carbohydrate) metabolism for the patient. This provided unheralded accuracy in the adjustment of the nutritional support of the ventilated patient in terms of total caloric needs and substrate mix, as well as appropriate ventilator settings management.

corporation.

During this time I really "grew-up" in the ways of the industry and started to realize that maybe there were better ways to do things that were not so encumbered by larger organizational structures and NIH[7] syndrome. I started to think that maybe innovative excellence could be achieved if there was less focus on the process and more on the outcomes and customers? This concept was aptly illustrated by Abrahamson & Freedman (2008, p. 181) when they pointed out that "Instead of trying to figure out the best way to do something and sticking to it, just try out an approach and keep fixing it". I would say that at this time my entrepreneurial wings had started to unfold. Despite my clear frustrations, I stuck with it and attempted to change the culture from within. I continued to move upwards within the organization and ultimately ended up at the divisional group management level. During this period I gained extensive knowledge and participated in the leadership of the division, utilizing many of the skills I had acquired in planning, organization and not least communication throughout the business unit. For every new project, I had overall responsibility to research the market opportunity, assess the development costs and timelines, conduct financial Return On Investment (ROI) analysis and ultimately argue whether, or not, to move forward with the project. Once the project commenced, my department then had oversight of the R&D and regulatory submissions and then planned transition into manufacturing and the whole global release to sales, including developing all the marketing material and campaigns. Finally though, as the company was to be acquired for the third time, this time by the ill fated TYCO conglomerate that was then led by the now convicted Dennis Kozlowski (Ackman, 2005). I grew disillusioned with continually justifying my existence in an ever changing organization that seemed to lack focus and even more so direction. The time had come for me to leave my comfort zone and see if I could fly.

[7] NIH = Not Invented Here

2.3. Spreading my entrepreneurial wings

My first start-up venture was called eVent Medical Ltd., which was a company based on unique technology and a ventilator patent that I had jointly filed and was consequently issued (Griffiths & Daescher, 2006) that allowed for a ventilator to be controlled and monitored remotely utilizing a mini-web server over a Local Area Network (LAN). This was a revolutionary new approach and I was able to form the company around this core Intellectual Property (IP) and raise investment from Angel type friends and family investors to develop the ventilator and bring it to market as was highlighted in a periodical at the time (Lytle, 2005). This was a period of great change and learning for me, as I had to transition from the corporate world to the start-up world. One of the greatest challenges for me during this time was navigating the world of start-up finance, as after the initial angel round of investment, we needed to raise an additional investment and the financial markets became significantly tougher during this period.

Despite all the new challenges I faced being the Chief Executive Officer (CEO) and founder of my own company, this period was one of the most liberating in my career, as I was able to do things how I felt they could best be done. Not to say that I was always right, but with the formation of a strong team of professionals and innovative global quasi virtual infrastructure[8], we were able to quickly show what could be done with focus, Completing development, testing, regulatory approvals and releasing out first intensive care ventilator, aptly named the "Inspiration" to sales in less than 2 years. This product also followed the ethical approach discussed earlier and provided extensive high-end features at a price point that was affordable in most markets around the globe. We continued to grow the company and released various further products for 6 years until the company was sold to a multi-billion dollar Japanese conglomerate, Kobyashi Corporation (2007), This transaction not only resulted in positive financial outcomes for all the investors and vested employees, but also allowed for a much larger company to continue the legacy we had started and bring our product into the hands of an even greater number of clinicians around the globe. Calculated from my own eVent Medical Ltd. sales numbers and the annual reports of Kobayashi corporation (2010), on average, about four hundred Inspiration family ventilators have been sold each year, looking at the last nine years of sales and utilizing a 50% utilization rate and a conservative Ventilator Length of Stay within the Intensive Care Unit (ICU) estimate (T. Williams, 2008), this would equate to well over 150,000 patients that have been treated

[8] By quasi-virtual infrastructure I mean that the company had employees based at many different locations (many cases their home offices) around the globe and we communicated daily via internet, online conference calls and email etc., not that it was an cyberspace (internet) company only as the term commonly refers.

worldwide with one of my Inspiration family of ventilators.

Next I moved on from the respiratory and ventilator field into the wound care field with the formation of my current enterprise, Advanced Oxygen therapy Inc. This company is focused on developing and marketing Topical Oxygen therapy that incorporates another of my patented technologies (Griffiths, et al., 2009) that utilizes Oxygen in a topical application to heal previously non-healing wounds, including; Diabetic ulcers, pressure ulcers (bed sores), other chronic and acute wounds. This new entity required me taking my strong methodological approach and researching a completely different clinical specialty. Even though challenging, I found the process fascinating and have quickly become a subject matter expert in topical oxygen for wound care, having spoken at numerous conferences around the world (Griffiths, 2012). I heavily relied on my experience with my first start-up in establishing the structure for this new venture and a number of my former employees were happy to come along and join me in something new. Additional to the many common challenges discussed before, this opportunity has provided new challenges as our technology allows for easy patient treatment in the homecare environment where reimbursement is required for a therapy to be successful. The Centres for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group (2011, p. 2) estimates that Home healthcare expenses in the USA totalled approximately $110 billion in 2010 and accounted for an astonishing 1% of GDP. So the opportunity is enormous, as are the potential healthcare system benefits, as it is commonly accepted to be a far cheaper site of care than institutional alternatives. This being said, the bar for gaining reimbursement has been steadily raised over the years and in most major markets around the world the regulators require clear clinical outcome improvements over alternative treatment options, which involves costly Randomized Controlled Clinical Trials (RCT). Conducting the research to develop these trial protocols and then drafting them with the physician investigators has provided a new area of learning for me that has resulted in publication of the protocols and resultant trial outputs (clinicaltrials.gov, 2012). Additionally, as this business has grown and further investment funds were required to fund the clinical trials etc., I have had to develop various detailed business plans, investment schedules and complex financial models to present the opportunity to a varied broad selection of potential investment partners, which range from private equity funds, venture capitalists and traditional bankers. A process that has become progressively more difficult and taken up increasingly more of my time, since the global financial market meltdown in 2008 and access to funds have been significantly reduced. This is evidences by the National Venture Capital Association (2011) that estimates that there was a 54 percent Drop-off in venture industry fundraising from 2008 to 2010.

2.4. Subject matter expertise

Throughout my years in Product Management and then as entrepreneur, I continued to further my learning and love of teaching. The actual manner in which I taught migrated away from weeklong classes and more towards shorter conference presentations and half day seminars. This was driven somewhat by my changing role to that of an entrepreneurial executive, but also by my increased recognition as a subject matter expert. In the words of one great American president and visionary, Abraham Lincoln; "*I don't think much of a man who is not wiser today than he was yesterday*" (1809-1865) an ideal I have certainly tried to embrace. I have travelled extensively around the globe on speaking and business engagements, having presented at numerous congresses and symposia worldwide on a wide range of topics as detailed in my CV (Griffiths, 2012). The length and level of each presentation varies dependent on the content matter and the audience, but generally the lectures were between 1 hr – 3 hrs in duration. In most cases the audiences were business professionals, healthcare executives, clinicians or physicians in the medical device field. These presentations commonly required the introduction of new ideas, or approaches, that were then contrasted to existing evidence. In a number of cases this would have fostered new ways of thinking and direct new knowledge. These presentations were made available to all attendees of the conferences as handouts or in abstract books and were unrestricted for onward general public circulation (Griffiths, 1995 - 2012). The public impact of these presentations varies dependent on the content, material and audience. For example, at the 2010 Caribbean Healthcare Congress in the Cayman Island, which was attended by regional health ministers and professionals, I brought awareness to the Chronic Wound epidemic caused by obesity and diabetes. Introducing many startling facts about the impact on the quality of life and healthcare economics to that region, is today I hope positively influencing healthcare policy in the region (Griffiths, 2010). I cherish the thrill of presenting to a new audience and interacting with them in open dialogue. The skills I have established over the last 26 years provide me with the professional ability of a public speaker, that when combined with the knowledge I have been successful in absorbing, provides me the credibility as a product matter expert in my field of expertise. I expect to continue to learn and teach in some manner until I die.

3. Barriers To Successful Implementation of Innovation Within the Non-Invasive Medical Device Field

Merriam-Websters dictionary defines Innovation as "*1: the introduction of something new; 2: a new idea, method, or device*" (2012) and it is believed to have originated from the Latin in the mid 1500s[9]. Clearly this term can be, and has been, used to describe the introduction of new ideas, products or concepts in every sphere of human influence ranging from the social sciences to engineering (Godin, 2008). Another term that is also used in combination and originates from the same period is that of Inventor, which Rossman in his book entitled 'The Psychology of the Inventor' (1931) simply defines as one who "*creates or introduces something new"* (p. 25). In Denny and Dunham's excellent book on the subject titled 'The Innovator's Way' they explain that innovation and invention are related but different insomuch that the practice of invention is related to the early stage of overcoming a problem, or creating an opportunity, whereas the practice of innovation is related to taking the offering provided by the invention through the adoption stage into the community (2010, p. 8). Especially in case of medical device technology there is no shortage of inventors that come up with innovative new products, or approaches to a problem, that never make it into the marketplace due to their inability to overcome any number of the barriers to entry. Marketplace implementation of such innovations is then critical, I believe, in order for the innovation to be deemed a success as it does no good for mankind to leave it on the shelf to gather dust.

My analysis and discussion that follows will focus on the specific barriers that need to be overcome in taking an innovative idea that has been developed into an early stage product and implementing it successfully into the marketplace within the non-invasive medical device field[10], from the perspective of the practitioner, which in this case is the innovator and implementer. I will not be looking at the inventive stage itself, but more at how to take an innovation forward from this stage to successful marketplace implementation. I will illustrate the process by citing examples from my own public works of how I addressed and overcame these barriers with a couple of specific innovations. I will not focus on the operational and financial challenges of running and

[9] Not surprisingly this being the middle of the Renaissance period and scientific revolution when the likes of arguably the greatest "Innovator" ever, Leonardo da Vinci, were in their heyday. (Lemelson-MIT Program 2004)

[10] Medical devices can be split into two main categories; "Non-Invasive" meaning they do not go within the body and "Invasive" meaning they go into the body. The regulatory pathway for Invasive product is somewhat similar to that of Drugs and is distinctly different to that of non-invasive devices. I focus on the later as this being my area of expertise.

funding the business, but will defer that to the next chapter, where I will thoroughly detail my distinct contributions and their impact in the field.

In the table that follows, I have outlined the general barriers that every medical device innovator must overcome when looking to implement their innovation. This is not meant to be an exhaustive list but a general outline of the most significant factors and I will then elaborate further on each key component as they relate to my public works experience and professional practice.

Medical Device Barriers to Innovation Implementation		
	Barrier	**Challenge**
a.	Achieving and maintaining an adequate Quality System	The initial barrier to entry is that you must comply with any array of quality system requirements throughout the world
b.	Transferring the design from prototype phase to manufacturing	Innovating in the laboratory is only one step. Making sure the design is manufacturable is more difficult.
c.	Gaining regulatory clearances for the device	There are distinct regulatory clearance channels and processes that must be followed within the USA, European Union, Japan and most countries worldwide in order to market a device legally.
d.	Establishing distribution channels	With regulatory clearances in hand you now need to establish your route to market.
e.	Gaining reimbursement for the device	Regulatory clearances are the "Ticket to Play". Reimbursement is often required to make any money from the endeavour.

3.1. Achieving and maintaining an adequate quality system

The concept of quality systems evolved out of the Industrial Revolution in the 18th century, which resulted in an outpouring and sustainability of inventions (Smith & et. al, 2004). The resultant exponential growth in technology and towards mass production, and away from individual skilled craftsman that built an item from start to finish, necessitated that quality be overseen by someone in order for it be consistently maintained. This concept morphed further over time and was tailored by quality control professionals to every type of manufacturing and industry. It's surprising that although

manufacturers would internally follow quality control processes, that formal quality systems in the medical device field did not become mandatory until the 1980s, despite being in place for drug manufacturers at least a decade before. Throughout the following three decades these quality system regulations went through various changes and consolidations, including migrating from individual country specific standards to more harmonized regional standards, something that was significantly achieved by the formation of the European Union.[11] In general quality systems comprise the simple elements of saying what you will do, doing it as you said you would and documenting that you actually did it.

You cannot market a medical device within the USA, European Union or pretty much anywhere else in the world unless you achieve and maintain compliance with the appropriate quality system standards. For many people this task can be overwhelming as the depth of the standards seems on first glance to be excessive. However, with a systematic and pragmatic approach, compliance can be achieved. This involves developing procedures and documentation for all aspects of the business and implementing these procedures on a daily basis. In my first start-up enterprise, eVent Medical Ltd., I personally took on the task[12] of attaining compliance to these standards and recall vividly how much work was involved in drafting all the procedures and required forms and documents. I would spend countless late nights trying to apply the regulations to my specific new venture and innovative ventilator products that we were developing, such that the procedures were not just there on paper, but were actually effective in their purpose for our small company. This is evidenced within my public works quality system manual (Griffiths, 2001). I strongly believe that ethically, you cannot just pay "lip service" to quality systems by one time developing a "cookie cutter" quality manual with all the procedures neatly aligned per the standards, as this is a recipe for disaster. You need to work within the framework of the regulations and adapt the procedures to suit your very specific business needs and continuously re-assess and make changes to them, as your business is not a static entity and the quality system should evolve as it does. As detailed by the Global Harmonization Task Force (Rotter, 2008) report, this concept of active implementation is also becoming an area that regulators are paying more attention to in the quality surveillance audits as well.

As Burr points out in his report titled "Quality System Development in Medical Device

[11] For most of the initial decades, these standards were the protected domain of a country's official standards organization, for instance British Standards in the United Kingdom, to develop and regulate the rules, something that was difficult for them to give up for harmonization's sake, until mandated due to the European Union formation.

[12] I took on this task out of necessity as the company originally only had 2 employees.

Start-ups" (Burr, 2004) the Quality Systems themselves, although there are some minor differences, primarily address the aspects of designing, manufacturing and marketing of medical devices. They tend to be broken down into the general categories of Design Controls, Production and Process Controls, and Post-market surveillance.

The two main regulations that have solidified in the last decade are;

3.1.1. International standards organization (ISO) 13485:2003 medical devices - quality management systems

This is an evolutionary standard[13] that has been adopted by the European Union and the majority of countries outside of the USA. Compliance to this standard is the minimum required to manufacture products to market in these countries, along with certain country specific additions. Unlike the USA requirement discussed below, attainment and compliance to this ISO standard is achieved by annual physical audits of the company by a duly authorized entity, which are referred to as a notified body. These notified bodies can be either government standards organizations, such as BSI in the United Kingdom or TUV in Germany, or private certification companies, such as SGS and MedCert etc.

For the innovator, it is not only important to develop the documentation and systems to comply with Quality Management System standard, but they also have to decide the most appropriate notified body to contract with. It's clear that although these bodies are required to audit to the same regulations, there is room for individual interpretation and approaches. This raises potential ethical dilemmas for the innovator, as on one hand you might want to utilize the most thorough notified body in order that your quality system is assessed as effectively as possible, but on the other you don't want to be subjected to audits and interpretations of the regulations that are overly punitive and raise too many unnecessary corrective actions. Another consideration is that of cost, as by effectively opening up this function to an open-market approach, you have all these notified bodies competing for your business. I have struggled with this issue in both of my start-up entities, having used both private and governmental bodies in each. My decision process was based on such factors as the nature of my products to the entity's expertise, the manufacturing site location relative to the body and of course the cost consideration. The problem is that even though

[13] Evolutionary in the sense that the standard is updated occasionally and when a new version is released the year of that release is included in the title of the standard itself, hence ISO 13485:2003 is the current active release.

you can freely change from one notified body to another, it's easier said than done as it also impacts your product's regulatory approval for CE mark and this is a much more complex and time consuming issue as you will see later on.

It's also become painfully evident that some are clearly more vigilant than others, as is expertly pointed out by Stewart Eisenhart (2012)in his article in Mass Device that discusses the obvious oversight shortcomings by the notified body in the case of the French breast implant manufacturer, Poly Implant Prothèse, resulting in the European Health and Consumer Policy Commissioner, John Dalli, demanding tighter vigilance and the notified body verification

3.1.2. US Food and Drug Administration: 21 CFR 820 quality system regulations

The regulatory oversight for medical devices in the USA is conducted by the Food and Drug Administration (FDA), a federal government agency within the U.S. Department of Health and Human Services.[14] The FDA requires most medical devices to be developed under design controls and within a quality system.[15] Unlike the ISO standards discussed above, the FDA does not proactively audit medical device manufacturers of non-invasive devices for compliance to these regulations; instead the manufacturer is required by law to state their compliance and maintain current registration of the company and cleared devices within the FDA databases. So here the onus is put onto the manufacturer to be compliant.

The FDA does however execute random audits of medical device companies, which can be conducted by any of the local or regional offices. Historically, lower risk, non-invasive medical device manufacturers were unlikely to be audited unless their devices had been involved in a corrective action or recall. This resulted in what many people believe to be a dichotomy of oversight, which was even further exasperated internationally by the lack of international audit resources within the FDA, meaning foreign manufacturers were even less likely to be paid a visit by an FDA inspector. It also meant that as an innovator you would fear an FDA audit as it was usually preceded by a problem. To help alleviate this perception and help manufacturers prepare for an audit the FDA

[14] Per the FDA website (2012) the agency employs over 11,500 personnel.
[15] Dependent on whether the device is classified as Class 1 - 3 dictates the level of quality system requirement. The higher the risk the device the greater the depth the quality system needs to cover.

established guidelines for inspections of foreign medical device manufacturers (FDA, 2010). More recently the FDA has also announced it has stepped up its auditing and inspections of foreign companies (HealthDay News, 2011). I can personally attest to this trend having had my Irish based company audited by the FDA in 2011 without any preceding incident.

Even though there has been a lot of focus over the last ten years on trying to harmonize worldwide quality standards into one regulation, a Global Harmonization Task Force was formed in 1992 that includes members from all the major regulatory bodies around the globe and this task force has issued numerous recommendations and talking papers (Rotter, 2008), but to date has been unsuccessful in moving much closer to a global harmonized quality standard. In large part due to the nature of the regulations, that is enshrined into the laws of each individual country, but also due the vested interests of the various competent authorities in the different jurisdictions around the globe. That being said, I believe strongly that these efforts need to continue as anything that can be done to standardize and simplify the global framework for medical device manufacturers and help innovators navigate the current convoluted web of regulations, would go a long way to improve compliance and efficiencies. Not to mention the potential cost saving benefits that would come out of streamlining this enormous barrier to innovation implementation. This is an area that I advocate during my speaking engagements and by my membership of various industry associations, such as the Medical Device Manufacturers Association etc as detailed in my CV (Griffiths, 2012).

3.2. Transferring the design from prototype phase to manufacturing

The process of design and technology transfer into manufacturing is commonly underestimated by inventors as their focus tends to be on the inventive step itself. The attention to detail and skills required to achieve manufacturing success has resulted in the establishment of specific design transfer and manufacturing engineering specialties. Khandani states that “Engineering is the creative process of turning abstract ideas into physical representations” (2005, p. 4), so by this premise, design transfer and manufacturing engineers take the physical representations that the inventor has evolved out of abstract ideas and makes them into something that can be reproduced. In other words, these experts take innovations and complete the metamorphosis from prototype to a manufacturable product and do so while maintaining compliance with the required quality system and regulatory standards detailed in other sections. In most

cases these engineers are also responsible for developing adequate procedures and documentation to cover the processes involved in a controlled and verifiable manner. So the importance of inventing and designing medical products with manufacturability as a key concept at the earliest stage should not be underestimated, otherwise you may end up with a great invention that is impractical to make and effectively useless to the real world. To coin a phrase from Dr. Covey's second habit of highly effective people; "Begin with the End in Mind" (Covey, 1989).[16] In the next chapter I detail my contribution in this area with a number of my public works that demonstrate the importance of this concept and were thereby implemented more effectively into the marketplace.

3.3. Gaining regulatory clearances worldwide

Like with the Quality System certification process discussed previously. There are two predominant regulatory clearances required to market a non-invasive medical device worldwide. These are the US FDA 510(k) and European Union CE mark. With these clearances obtained you are able to market your product within the USA and European Union, and you can utilize this to gain similar status in the majority of other countries, with Japan being an exception as it has its own dedicated process called Shonin. For the innovator, navigating the myriad regulations and gaining these approvals is daunting, but is a requirement if you want to legally market your device. It is evident as detailed in the table below that the primary focus for most medical device companies are the USA and European Union marketplaces, as combined they account for close to $200 billion in annual sales and approximately 80% of the worldwide medical device market (Espicom, 2011). However, like with other goods, the importance of the Asian and South America countries is growing as their economic development and resultant spending on healthcare continues to increase.

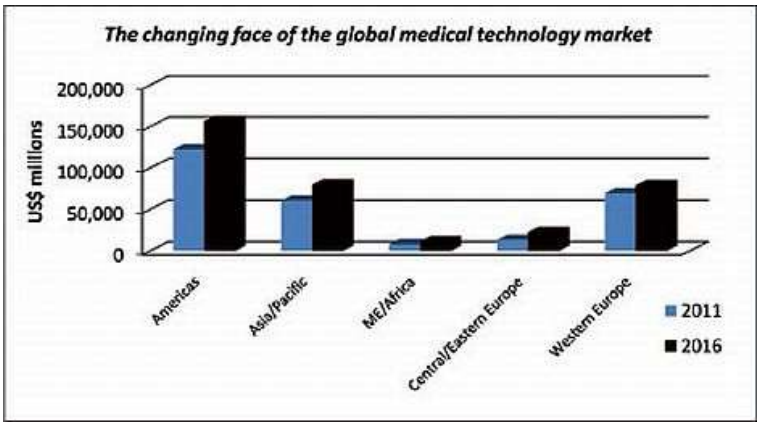

Figure 1. Worldwide Medical Markets Forecast to 2016 from ESPICOM (2011)

[16] It is interesting how many parallels can be drawn between the business and life skills ideals

I will focus on these two main regulatory clearances in more detail below, but again the harmonization of regulatory pathways, would like with quality system pathways discussed previously, have huge potential benefits if the powers to be would allow it to happen.

3.3.1. European Union CE mark: medical devices directive (93/42/EC)

The medical device directive outlines the rules and approach needed to assess what category (or class) a device falls into. From this the required regulatory hurdles are determined. There are four classes for medical devices, progressing from 1, 2a, 2b and 3 and with class 1 being devices posing least risk and class 3 the most. As you would imagine the approval pathway is more involved in devices of higher risk then in ones with less perceived risk.[17] The majority of non-invasive medical devices fall into class 2a and 2b and there are a couple of different approaches (annexes) that a company can take to gain approval based upon their structure, quality system status and expertise. For both these classes, the innovator must develop what is referred to as a "technical file" and submit this for approval to their notified body. The technical file contains a declaration of conformity and classification assessment, all the design specifications and verification tests results, details of adherence to the essential requirements of the directive including any specified standards for the type of device, a detailed risk analysis and a clinical assessment. Unless the device is of a completely new nature, there are no requirements to conduct clinical trials, as long as you conduct a detailed clinical literature review and address any questions of safety in the risk analysis. As you can see the onus for the approval is on the company and the actual approval is given by the notified body as a conformance of the product to the directive within the quality system framework. This approval is limited to usually three years and is then assessed again at that expiration, primarily for adherence to changes in the regulations and for updated risk analysis. Once this certification has been achieved, you can apply the CE mark to your product and it can be freely marketed within the EU[18]. It is also important to point out that the product approval is only valid as long as your quality system

[17] This is also mirrored in the Quality system requirements, where higher classification devices require more stringent oversight and control processes.

[18] The CE mark for devices of class 2 or higher include a number that designates the notified body, for instance our CE mark for our wound oxygen therapy system is CE 0050, with 0050 being the National Standards Authority of Ireland's duly designated Notified Body identification number, for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)

is in compliance and this is assessed annually.

3.3.2. US FDA 510(k) per 21 CFR 807.92(a)(3).

In the USA medical devices are classified as either class 1, 2 or 3, with devices posing most risk in the higher category. Most devices that are class 2 and some that are class 1 require the submission of what is called a 510 (k) Premarket Notification. The FDA refers to this approach as risk based oversight and its various components are shown in the graph below (Pate & Watson, 2011).

Figure 2. Risk based Oversight from *Food and Drug Administration Overview of Medical Device Regulation (2011)*

Similarly to the CE mark, a 510(k) is a formal premarket submission packet made to the appropriate centre within the FDA. Most commonly for non-invasive devices this will be the Centre for Devices & Radiological Health (CDRH). However, instead of showing conformance to certain essential requirement regulations, in this case the purpose is to demonstrate that the device to be marketed is “substantially equivalent” to a legally marketed predicate device. Demonstration of substantial equivalence fundamentally means that the new device is at least as safe and effective as the predicate, in such that; it has the same intended use; and has the same technological characteristics as the predicate. It is acceptable for the device to have same intended use as the predicate but with different technological characteristics, as long as this does not in the opinion of the reviewer raise new questions of safety and effectiveness. So a claim of substantial equivalence does not mean the new and predicate devices

must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, standards, and other characteristics, as applicable (U.S. Department Of Health And Human Services, 2010). So if this can be established with adequate detail and supporting test data etc. to the reviewer's discretion, then they will issue a premarket notification letter and you are cleared to legally market the device within the USA.

As was pointed out by an eminent Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (2011) in a report on the topic; like with the CE mark, for lower risk classification devices, no clinical trials are required to gain US marketing clearance. This is a topic that has recently created some controversy in the general public as to whether medical devices should be cleared through the 510(k) process without the need for on patient clinical data. This issue was stirred up by awareness that a number of hip implants that failed and required removal had been cleared to market through this route (Meier, 2011). There is always a balancing act between having adequate opposed to burdensome regulations, which normally always comes down to a risk to benefit analysis. This topic raises a number of ethical considerations. Clinical trials are incredibly expenses and many products would simply never make it to market and be allowed to help needy patients. Of course this has to be tempered with the premise that we do not ever want to do harm to a patient. But I am not sure that clinical trials necessarily provide a guarantee of no harm, as there are many drug products recalled (Celebrex and Viox come to mind recently) from the market after terribly harmful side effects were discovered, that had all gone through extensive phase trials for safety and efficacy prior to being approved.

It is my opinion, and that of all the industry trade groups such as ADVAMED (Advamed, 2012) in the USA and EUCOMED (Eucomed, 2012) in Europe, that requiring lower risk devices to have in-vivo[19] clinical data as part of their regulatory submissions would be enormously damaging to the entire healthcare system and would stifle innovation. No premarket regulatory system for medical devices can guarantee that all new medical devices will be completely safe and effective when they reach the market. This view is also supported by the

[19] In-Vivo refers to within the body or on patient

eminent committee that was formed by the Institute of Medicine[20] to study The Public Health Effectiveness of the FDA 510(k) Clearance Process (2011) and which concluded that "No premarket regulatory system for medical devices can guarantee that all new medical devices will be completely safe and effective when they reach the market. Robust post-marketing surveillance is essential". The committee also went on to state that the "current 510(k) process was flawed based on its legislative foundation" and should effectively be scrapped allowing the FDA to better allocate its resources towards a new framework that would better address safety and effectiveness across the device's life cycle. The FDA firmly rebuked this idea.

As I described earlier, in my first start-up I personally managed and completed all the regulatory and quality requirements for the business. An example of this from my public works is my submission for and resultant approval of the 510(k) marketing clearances for the Inspiration[21] Ventilator (Food and Drug Administration, 2002), this submission summary are openly available to the public via the FDA website (FOOD AND DRUG ADMINISTRATION, 2012) and with a request for information, the entire submission can be provided to any interested party. This public domain documentation availability is invaluable I believe as part of the ongoing sharing of knowledge within the field and by its very nature imparts new learning. This information is also helpful in making sure that companies conduct their advertising and promotional activities ethically and only market their products for their approved intended-use. Sweet and colleagues (2011) looked at this issue in detail and concluded that misbranding or mislabelling of medical devices, be it unintentionally or by design, is a problem that is becoming only too common within the industry. The following chart succinctly summarises the main differences in the Quality systems and Regulatory requirements between the two transatlantic continents:

[20] The Institute of Medicine serves as adviser to the nation to improve health. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policy makers, health professionals, the private sector, and the public

[21] A registered trademark of eVent Medical Inc.

Figure 3. Quality systems and Regulatory requirements between the two transatlantic continents: (Cittadine, 2010)

3.4. Establishing distribution channels

It is critical that once you have the medical device ready to ship and the regulatory clearances to market it, that you establish appropriate and effective distribution channels. In general marketing terms this encompasses at least one of the founding four Ps[22], namely; Place, a concept first proposed by the eminent E. Jerome McCarthy (1960). This barrier to success should not be underestimated as many products have failed to meet expectations due to an inadequately thought out strategy. Distribution may be established in many different ways dependent on the type of product and resources available to the company. In most cases it is necessary for an innovator to partner with experienced regional or national medical device dealers or distributors, especially in foreign markets. This allows for a multiplication of resources and a focus on the relative areas of expertise of each party. It is reasonable that over time and as the business grows that the distribution approach should be adjusted and in many cases will evolve at a point of critical mass in the core home markets into a direct organization. I will elaborate further on this barrier and cite examples from my own experiences in the next chapter.

3.5. Gaining reimbursement for the device

With the aforementioned barriers being addressed it is time to start taking-on possibly the biggest obstacle to success; reimbursement. That is not to say this should be left to the end, on the contrary it should be paramount as part of your business strategy. There is no universal model to how medical devices are paid for or reimbursed; instead each country has its own approach.

[22] Price, Product, Promotion and Place

There are also major demographic trends that are shaping the healthcare reimbursement landscape in its entirety. The increasing proportion of elderly population caused by the baby boom after the last world war and much improved life expectancies, combined with skyrocketing per capita healthcare spending costs and the rise in chronic debilitating and expensive diseases, such as Diabetes, Obesity, Asthma and COPD,[23] are all creating a perfect storm of spiralling healthcare costs that will sink our global economies if not addressed by the policymakers. The U.S. Centres for Medicare and Medicaid Services, Office of the Actuary, "National Health Statistics Group" (2012) estimates that healthcare expenditures exceeded two and a half trillion dollars in 2010, with 45% of this massive amount being paid for by government programs such as Medicare and Medicaid, 40% by private insurance, and the remainder out of the pockets of the patients directly.

It also depends on the nature of the medical device as to whether reimbursement is a direct or indirect concern for the innovator. By this I mean that if the product is an expensive piece of capital equipment targeted for hospital use, then specific reimbursement is not usually required to be able to go-to-market as these types of products are usually amortized under a hospital's capital budget and not charged back to a payer on a fee-for-service[24] basis, but instead bundled into a prospective or capitated payment for treating a particular condition etc. So for these products the sales strategy hinges around a traditional competitive price and feature set to convince the purchaser to chose your product over an alternative. Conversely, products that are targeted into the homecare or physician's office environment are commonly charged back to the payer on a per-use or utilized specific fee-for-service basis. In these cases, until you have reimbursement established you have no sales at all.

3.5.1. Reimbursement in the USA

There are several organizations within the USA that are involved in establishing reimbursement rates for reimbursed medical devices. The primary entity is the Centre for Medicare and Medicaid Services (CMS). This agency was formed in 1965 and today administers both the Medicaid (program for the poor and disabled) and Medicare (senior citizens over 65) programs that combined account for the majority of all US health expenditures and close to 800 Billion dollars, or 24%, of the entire Federal budget in 2010 according to the Medicare

[23] Chronic Obstructive Pulmonary Disease (COPD)such as emphysema and bronchiolitis from smoking and pollution.

[24] Fee for service relates to the approach of charging for a specific item or procedure once utilized

Spending and Financing Primer published by the Kaiser Foundation (2011). By default anything that is covered by CMS is also covered by the Private insurance companies as they effectively let the agency act as the gate keeper.

The process of gaining CMS Reimbursement requires that you petition at the national or one of the four regional levels for a coverage determination. The coverage and analyst group within CMS then initiates a process as detailed in the table below. The primary assessment criteria are simply sufficient confidence exists that the product or service "improves health outcomes generalisable to the Medicare or Medicaid population" (2012). To reach these conclusions the agency utilizes a strict evidence based medicine approach[25]. Therefore, it is virtually impossible to get reimbursed for a new medical device without at least one well thought out Randomized Controlled Clinical Trial[26] that shows a positive outcome over an existing treatment regime. Due to the complexity of ethics committee approval and the high per patient trial costs in the USA, there is a clear trend to conduct clinical trials in less burdensome and less costly regions, such as Europe, especially in the eastern European Community member states like Poland, and also in India.

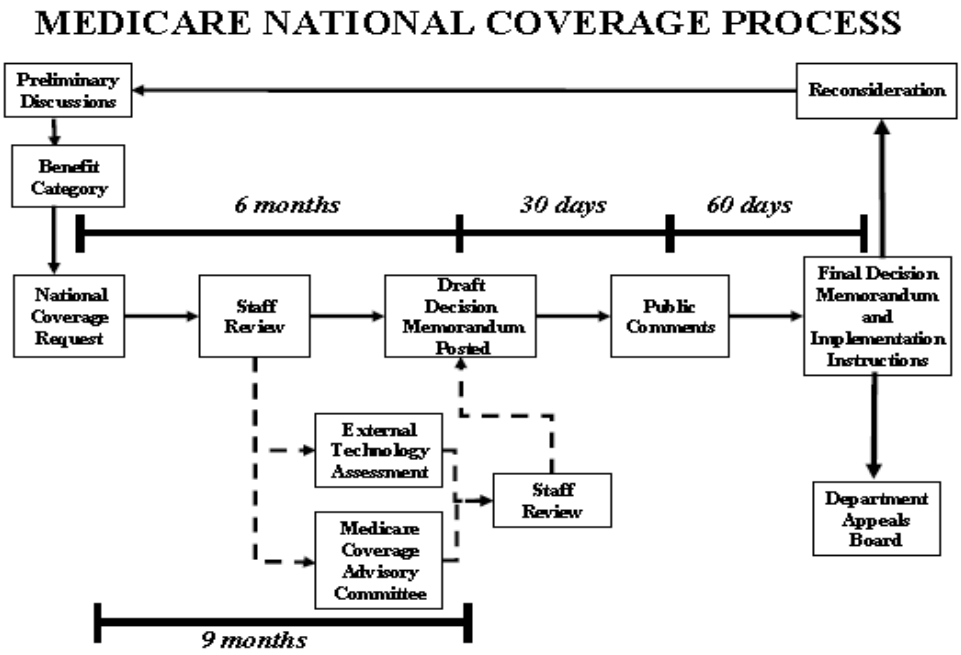

Figure 4. CMS Coverage Determination Process, CMS Website (2012)

[25] Evidence based medicine relates to making clinical decisions based on the outcome evidence from controlled clinical trials and not on gut feeling or personal conjecture.

[26] By well thought out I mean that it should have appropriate clear primary outcomes that are proven with sufficient weight to be deemed statistically significant

So even though clinical trial data is not required for regulatory approval, you can see that it is critical for reimbursement if that is a factor for success with a particular device. Because it is prohibitively expensive to conduct these trials until the device has regulatory approval, most companies commence them at that stage, resulting in a common time gap of two to three years from release to sales of a device before being able to get reimbursed. This is an issue that is very difficult for small companies to manage and stay financially viable, especially when you consider that a small 100 patient randomized clinical trial may cost upwards of $1 million to conduct.

One of my public works examples that illustrate this area is the protocol and study manual for a clinical trial developed in 2008 for our unique Topical Wound Oxygen device for use on diabetic ulcers (Griffiths, 2009). The process of drafting this manual and developing all the associated documents; tracking forms and study manual for the investigators etc., required months of intensive research into not only expectations of the reviewing agencies,[27] but also into the diabetic ulcer clinical field included extensive review of other trials in the same field . It also involved a certain amount of statistical analysis to calculate adequate sample sizes based on likely outcomes etc. Like all clinical trials conducted in the USA, the protocols have to be published online in the US governments clinicaltrials.gov (National Institute of Health, 2012) database and are publicly accessible to anyone who wishes to view them. This project was significant to me in that I was able to master new skill and gain new knowledge in that area.

There are some unique government agencies, such as the Veterans Administration, where medical devices are procured from the Federal Supply Schedule (FSS). A distinctly separate process is followed to get listed on the FSS and awarded a 5 year contract, which involves extensive product comparison and utilization data, but does not require clinical trials to prove outcome. In the case of the Topical Wound Oxygen product line discussed previously, I was successful in the process and my company was awarded a 5 year contract that allowed for fair reimbursement of our devices on both a direct purchase and rental basis. (DEPARTMENT OF VETERANS AFFAIRS, 2009). Like many start-up companies this target market segment has provided the company with adequate repeat business to survive and grow while investing in the larger clinical trials needed for broader coverage.

[27] I use the term agencies as I developed this protocol to meet the requirements of not just the USA CMS agency but also that of various European reimbursement bodies as well

3.5.2. Reimbursement in Europe and internationally as a whole

In Europe and especially within the European Union countries, each country manages their own healthcare expenditures and system. Most of the countries are dominated by a socialized medicine approach be it centrally funded like the iconic National Health Service (NHS) in the United Kingdom, or funded by government but administered via private insurers like in Germany. Universally though the same evidenced based medicine approach is used to grant reimbursement for devices, in that you require at least one well thought out Randomized Controlled Clinical Trial that shows a positive outcome over an existing treatment regime. The UK National Institute for Health and Clinical Excellence (NICE[28]) is a prime example of how the European agencies have also been including health economic data in their decision process, as it takes a relatively inflexible and formalistic approach to health technology assessment that is based on the concept of the cost per quality-adjusted life year. (Castle & Kelly, 2010)

The difference is that many of the reimbursement decision makers are increasingly expecting to see some of the in-vivo data collected on patients within their borders, making the design of the clinical trial plan even more difficult for a start-up company, as they now need to consider utilizing multi-centred and multi-national studies when gathering their outcome evidence, or potentially face being forced to repeat these costly trials.

Outside of the European Community there are various reimbursement structures that are either predominately government funded or a mix of low end government funded care with high end private care for those that can afford to pay. In any case, if the need for reimbursement exists in any of the countries the same challenges and approaches outlined previously would need to be adopted on a country specific basis by the innovator. One exception to this structure is Saudi Arabia and the Arabian Gulf region as a whole, where due to its extensive current wealth and ballooning healthcare service need, there is a net result of a five-fold estimated growth rate in total health-care spending in the region by 2025 when it will reach US$60 billion (Mourshed, et al., 2011). As the region is investing enormously in healthcare and is predominantly a direct purchaser of equipment without requiring any kind of reimbursement, but just the award of a tender for the goods, this opens up simpler opportunities for new devices.

[28] An unfortunate acronym for an agency that has a reputation for saying NO to reimbursement requests

A general trend that is being seen globally in many countries around the world that are all experiencing the same skyrocketing costs of health care, is that many are addressing this issue by such draconian approaches as simply reducing reimbursement rates or establishing price caps, without much logical thought for the impact to the caregivers and device manufacturers. This knee jerk approach although somewhat effective initially does nothing to get at the root of the problems and penalizes in many cases those that rely on the care most, whilst waste and misappropriations continue elsewhere.

4. My Contributions to Implementing Innovation More Effectively Within the Highly Regulated Non-Invasive Medical Device Field

4.1. Defining Innovation Implementation

Over forty years ago Myers and Marquis (1969) concluded that; "*Innovation is not a single action but a total process of interrelated sub processes. It is not just the conception of a new idea, nor the invention of a new device, nor the development of a new market. The process is all these things acting in an integrated fashion"* (Trott, 2005, p. 15)[29]. From my review of the literature on implementing innovation contained in appendix 1 it is evident that in order for innovations to be successful, especially as they are related to new technological products, they (the innovations) must be developed through an organizational process that is managed such that the more individualized entrepreneurial R&D efforts are aligned appropriately with the business's strategic leadership, goals and the various important market drivers (France, et al., 2011). Managing the innovation process through all the stages and spheres of influence while taking on the inherent risks is really what entrepreneurship is all about. France et al go on to say that the *"development and implementation of ideas that create value (is) the essence of effective innovation"* (2011, p. 52). This definition is notable in that it introduces the importance of value creation in assessing if an innovation is actuality effective. Despite this clear underlying theme in the literature, Tidd (2006) points out that there still seems to be some disparity, especially between the organizational and product/technological fields, as to exactly what is meant by the 'Implementation of Innovation'. Predominantly throughout the newer models of innovation, 'Implementation' is proposed as the final stage of the process, that follows both the Innovative stage (design, development and production), and the Adoptance stage (market release and initial use) (Austen & Martin, 2002), (Godin, 2008). However, the term is also used to refer to the entire process of taking an innovation (idea) through its earliest deployment stages, through market release, and then into its long term utilization (Jessup-Ange, 2009). Whatever definition you use, it is clear that ending the innovative process at the adoptive phase will result in failure. This is particularly evident for technological innovations. Peslak et al (2007) go to great lengths to emphasize this in their detailed review of the literature, which showed that up to 30% of technological innovations never get implemented despite being initially adopted.

[29] MYERS, S.; MARQUIS, D.G.; Successful industrial innovation: a study of factors underlying innovation in selected firms, National Science Foundation, NSF 69-17, Washington DC 1969 quoted in TROTT, P.: Innovation Management and New Product Development, 3rd edi-tion, Prentice Hall, Harlow 2005, page 15

Many researchers, including; Christensen et al. (2004), have concluded that small companies tend to be the most innovative and commonly provide an organizational environment that is more conducive to innovation. Tidd and Besant (2004) emphasize the importance of developing an organizational culture that facilitates radical innovation, opposed to just incremental innovation. Berkun in his book, The Myths of Innovation (2010), states poignantly that innovation results from good knowledge that is based on lived experiences, further supporting the notion that there must always be a practical real world component for the idea to truly be innovative.

In their paper looking at the inherent tensions that exist between Innovation and its Implementation, Austen and Marten state it well when they say *"organizations that foster creativity, visionary leadership, fast-cycle learning, and flexibility should respond effectively to the pressures of today's innovation-driven marketplace"* (2002, p. 8). This paper goes on further to implore that innovation alone is not enough and should be accepted as a prerequisite, and that effective adoptance and implementation are key to a business's success. More recently, Muna Kalyan (2011) explains that innovative organizations are by their very nature organized to take on risks and manage constant change. He elaborates that distinctively such organizations "*puts knowledge to work on products, processes, technologies, and markets, and eventually on knowledge itself*." (2011, p. 84). The literature consistently supports the concept that the key to achieving this in an organization requires an environment conducive to innovation and that incorporates four facets; culture, organizational structure, people and technology (Fiates, et al., 2010). Consequently, Druker's (1985) adages still hold true when he simply summates that innovation implementation and entrepreneurship are all unequivocally linked.

To assess the validity of my claim, we need to first define what is meant by Implementation of Innovation relative to my specialized field of expertise, namely; the non-invasive medical device field. Based on the brief discussion above and my review of the general literature on the subject contained in Appendix 1, I believe that in this case the implementation of innovation should best be considered in its broader technological context, that being; the complete process of developing an Innovation by overcoming all of the varied barriers (development, regulatory, finance, marketing and business etc.) to successfully implement it into the marketplace, which is consistent with the definitions by the likes of; Rhodes and Wield (2000), Austen and Marten (2002), Klein and Knight (2005) and Singhal and Dearing (2006) to name a few. Effective implementation can then be thought of as achieving appropriate committed use of the innovation by a primary target user as Klein et al. (2005) (1996) so aptly espoused. I think this definition

is most appropriate as it provides a direct measure of real market (user and clinical) effectiveness of the innovation and the process that brought it to market within a specialized field.

4.2. More effective implementation of innovation from my public works

In the remainder of this chapter I will explore my public works and related evidence, with focus on how they support my claim of making a *unique contribution* that has had *significant impact* within my field of expertise, and specifically will show that I have *implemented a number of innovations more effectively within the highly regulated non-invasive medical device field.* I will also further elaborate on how I have predominantly achieved my claim by establishing and managing small innovative and uniquely structured enterprises along the lines of those depicted by Christensen et al. (2004), which by their very nature epitomize entrepreneurship. Utilizing the definition of effective implementation established in the opening section of this chapter and analyzing my claim in its entirety, I believe it is useful to break the analysis down into distinct component parts, which can then be reflected on individually as they relate to my claim for the innovation in question.

A critical element of an effective implementation process is identifying innovations that address proven needs, a concept strongly supported by France et al (2011) with their insistence on the importance of value creation from innovations. Therefore, I have started my analysis here and once this prerequisite has been established, I will expand the discussion to address the effectiveness of their implementation. Following on from this we need to define what is meant by the term 'more effectively' in my claim. Simply put, effectively can best be defined as the implemented innovation producing the decided, decisive, or desired effect, which is commonly referred to as synonymous with the term 'efficiency' (Merriam-Websters, 2012). The European Commission in its report on Making public support for innovation in the EU more effective, offers up a definition of innovation efficiency as; that which "aims at ensuring maximum results with limited resources" (2009, p. 31) and then goes on further to differentiate this from innovation effectiveness, that they define as; "delivering what is needed on the basis of clear objectives, an evaluation of future impact and, where available, of past experience" (2009, p. 31). So to ultimately understand whether these innovations were implemented 'more effectively' than commonly seen within the non-invasive medical device field, we will need to compare them against the industry timelines, costs and to other user and clinical norms for such measures.

In the following sections I have detailed three specific innovations of mine from as examples from my broader public works. As an introduction, the following bullet points provide an executive summary of each of these innovations as they relate to my claim and as to whether the innovations were implemented more effectively than is normal within the field, these are then discussed in greater detail following this summary.

4.2.1 Executive summary

Were the specified Innovations Implemented more effectively than is normal in the field?

Public Works Example 1: Topical Wound Oxygen Therapy System and AOTI Inc.

Organization and product implementation effectiveness

- **Assessment criteria:**
  Reduced time and cost to implement the innovations into the marketplace than is normal within the field.

- **How was this achieved:**
  Established and managed innovative diversified quasi-virtual company that implemented the products quicker and for less cost than is normal.

- **How is this evidenced:**
  - Innovative company structure evidenced by my strategic business plan for the company (Griffiths, 2011) and company website (AOTI Inc., 2012) and by Distribution partner testimonials (USA and International Distributors, 2012).
  - Innovation was implemented within the global marketplace in less than half of the normal average 4 to 5 years timeframe (Kaplan, et al., 2004), (Combs, 2009), (Cittadine, 2010) and for a total capital investment in my company of less than $5 million as shown in my strategic business plan (Griffiths, 2011, p. 14), that is between 25% and 50% of the cost that is normal within the industry (Makower, et al., 2010), (Cittadine, 2010), (Shah, 2012), (Espicom, 2012).

Regulatory and reimbursement implementation effectiveness

- **Assessment criteria:**
  Achieving required regulatory approvals and reimbursement faster and for

lower cost than is normal within the field.

- **How was this achieved:**
  Competency focused approach and innovative company structure resulted in USA and European regulatory approvals and USA reimbursement being achieved faster and for lower cost than is normal.

- **How is this evidenced:**
  - Faster regulatory approvals and timelines evidenced by regulatory approval notifications; EU (National Standards Authority of Ireland, 2007) and in the USA (Food and Drug Administartion, 2008).
  - Faster reimbursement and timeline evidenced by Department of Veterans affairs contract award (DEPARTMENT OF VETERANS AFFAIRS, 2009).
  - Achieved in less than the low end of the normal two years and for no additional cost as evidenced by the my strategic business plan for the company (Griffiths, 2011), compared to the normal $2 million to $3 million for each major region sought (Espicom, 2012), (Makower, et al., 2010), (Kaplan, et al., 2004).
  - International Congress success press release (Doyle, 2010).

Clinical outcomes and healthcare cost saving implementation effectiveness

- **Assessment criteria:**
  The impact of the implemented product on healing wounds and reducing direct and indirect healthcare costs relative to other products in the field

- **How was this achieved:**
  Implemented innovation provides direct cost and healthcare system savings by healing wounds completely and more effectively with less reoccurrence in a lower cost homecare setting.

- **How is this evidenced:**
  - Wound healing effectiveness evidenced in multiple clinical publications and alternate therapy comparisons as evidenced by, (Sultan & Tawfick, 2010), (Derk, 2011), (Blackman, et al., 2010) etc., as well as in numerous clinician testimonials (Frykberg, et al., 2012).
  - The published extensive clinical trial protocol (Griffiths, 2009).
  - Cost savings evidenced by extrapolated Quality Adjusted Life Years (QALY) for the therapy of $2,475, compared to the cost per QALY of other alternate therapeutic modalities; $27,310 for Full Body HBO (Chow, et al., 2008), €24 881 for Negative Pressure Wound Therapy (Whitehead, et al., 2011)

Ethical implementation effectiveness

- **Assessment criteria:**
  Global implementation of a clinically significant treatment modality so that as many patients as possible can benefit.

- **How was this achieved:**
  By the resultant global clinical use of the innovation and the education of the community as to the scope of the problem and best treatment options.

- **How is this evidenced:**
  - Global clinical utilization evidenced by the growing and varied number of clinical papers; (Adler & Frye, 2012), (Blackman, et al., 2010), (Frykberg, et al., 2012), (Sultan & Tawfick, 2010) etc.
  - Over 1,000 patients have been successfully treated in the USA alone. This is calculated from the prescription orders for the therapy within the USA and number of treatments, and the duration of therapy provided. Approximately twice this amount has been treated globally. This is supported by the figures in my strategic business plan. (Griffiths, 2011, p. 4).
  - My presentations at conferences globally over the last five years as detailed in my CV and conference presentations (Griffiths, 2012).

Public Works Example 2: Inspiration Ventilator Product Family and eVent Medical

Organization and product implementation effectiveness

- **Assessment criteria:**
  Reduced time and cost to implement the innovation into the marketplace than is normal within the field.

- **How was this achieved:**
  Established and managed non-traditional diversified quasi-virtual company structure that implemented Inspiration ventilator family into the market in less time and for far less cost than is normal.

- **How is this evidenced:**
  - Innovative company structure evidenced by my strategic business plan for the company (Griffiths, 2005) and local newspaper article (Lytle, 2005).
  - Inspiration Ventilator implemented within the global marketplace in three

years and for a total capital investment of only 3 million dollars. This is less than the normal 4 to 5 years a timeframe (Cittadine, 2010) (Combs, 2009) and between 15% and 30% of the cost that is normal within the industry, (Kaplan, et al., 2004)**,** (Makower, et al., 2010)**.** (Cittadine, 2010), (Shah, 2012), and is supported by my strategic business plan and model for the company (Griffiths, 2005).

Clinical outcomes and healthcare cost saving implementation effectiveness

- **Assessment criteria:**
  The impact of the Inspiration product on providing clinical availability reducing direct and indirect healthcare costs relative to other products in the field.

- **How was this achieved:**
  Implemented innovation provides direct cost and healthcare system savings by providing high end clinical features in a more flexible low cost design making the device more economically viable for less developed markets and countries.

- **How is this evidenced:**
  - The Inspiration offers significant high-end performance capabilities at a price point of far lesser performing products as evidenced within my eVent Medical Strategic Plan (Griffiths, 2005, p. 24).
  - Viability for less developed markets demonstrated within the eVent Medical Strategic Plan by the sales mix of products being distributed throughout the globe with many sales into the lesser developed markets.
  - The Inspiration's Heliox and NIV feature can help wean patients off the ventilator quicker (Flynn, et al., 2010), (Venkataraman, 2006).Per patient ventilator days costs an incremental $1,522 (Dasta, et al., 2005), extrapolating these savings out shows that the Inspiration acquisition price could be offset entirely by just six patient ventilation days saved.

Public Works Example 3: The 7250 Metabolic Monitor Project

- **Assessment criteria:**
  The 7250 innovation provided significant clinical impact and was implemented within a shorter time then normal despite inconsistent resources allocation.

- **How was this achieved:**
  I managed a small focused team that developed the product and all

ancillary educational materials, and released it into the marketplace.

- **How is this evidenced:**
  - Clinical impact is evidenced by the innovations continued utilization across a widening gamut of conditions, as demonstrated in numerous clinical papers citing its use over the last decade; (Reid, 2007) (Faisy, et al., 2003), (Miwa, et al., 2003). (Brandi, et al., 1999), (Barco, et al., 1998).
  - The Clinical (Griffiths, 1996) and Technical (Griffiths, 1996) metabolic monitoring handbooks provide evidence of the clinical benefits and materials developed.
  -The 7250 was implemented in the marketplace in less than four years and for a minimal amount of capital expense allocation from the corporation, which is less than normally seen in field (Makower, et al., 2010), (Cittadine, 2010).

I will now elaborate in detail on each of the innovations summarized above, including identifying the innovation developed, the global health need addressed, and my associated public works in which it is evidenced. I will further explain and examine each of these innovations to assess its impact specifically as it relates to; the global health need that they purport to address, the details of the innovation that addresses such need, and the effectiveness of its implementation. Finally, I will answer the key question to my claim of whether the innovation was implemented more effectively than is normal in my field of expertise.

4.2.2. Topical Wound Oxygen Therapy (TWO_2)[30] System and AOTI Inc.

Innovation	Global Health Need Addressed	Evidenced within/by Public Work
Topical Wound Oxygen Therapy (TWO_2) System AOTI Inc. Company	Non-healing Chronic (Diabetic, Pressure or Venous related) ulcers and acute wounds	TWO_2 Patent (Griffiths, et al., 2009) TWO_2 Clinical Trial Protocol (Griffiths, 2009) AOTI Inc. Business Plan and Models (Griffiths, 2011) TWO_2 Product Datasheets (Griffiths, et al., 2012) AOTI Inc. Website (Griffiths, et al., 2012)

4.2.2.1. What is the global health need?

This innovation can be utilized clinically on a broad array of chronic and acute conditions as evidenced by the range of wounds treated, the resultant papers published in peer reviewed journals and those presented at the various international medical conferences, including those of the; European Wound Management Association and USA Vascular Surgeons (Blackman, et al., 2010), (Sultan & Tawfick, 2010), (Kivelä, 2010), (Adler & Frye, 2010), (Derk, 2011), (Kuspelo & Veikšina, 2011), (Adler & Frye, 2012). However, due to the enormity of the problem and lack of effective alternate therapeutic options, non-healing chronic (diabetic, pressure or venous) ulcers remain the innovation's core focus, as they represent the largest global health need within the wound care segment, afflicting as much as 3% of the global population (Nerac, Inc, 2007), resulting in a direct healthcare cost associated purely with their management[31] of over $55 billion annually (Medtech Insight, 2009). Current technologies and other therapeutic approaches do not address chronic wounds adequately and provide on average wound healing rates no better than 30%. (Medtech Insight, 2009). As much as 25% of all diabetic patients have chronic recalcitrant[32] ulcers (Whitehead, et al., 2011) and many ultimately lose limbs to amputation or even their lives to the resultant infections (IDF Diabetes Atlas, 2011). For diabetic ulcers alone, these associated costs[33] account for between 15% and 25% of the total healthcare resources

[30] Topical Wound Oxygen and TWO_2 are Trademarks of AOTI Inc.
[31] By management I mean treating and maintaining the ulcer but in the majority of cases not necessarily healing it
[32] Non-responding, Reoccurring, Non-healing
[33] Costs associated with; treating the wound, amputating the limb, post amputation care, prosthetics etc.

spent on diabetes as a whole ((WHO), 2005), or as much as $116 billion annually (IDF Diabetes Atlas, 2011).

4.2.2.2. What is the Innovation that addresses this need?

Appropriate Innovation identification is a critical element of an effective implementation process and the National Science Foundation in the United States points out the impact of research can be increased by moving the innovation to realistic deployment, linking new knowledge to economic growth and other societal benefits (Plimpton, 2012). This concept of understanding the customer's or segment's needs fully before embarking on developing an innovation has been extensively researched with the most effective innovators being shown to have created stronger ideas in the front end of the process, based on truly understanding their target segment's needs (Ross, 2009). The importance of developing Innovations that address real, opposed to perceived, needs, is paramount in my opinion, when assessing its impact in the field, but also its effectiveness.

To help address this enormous health need[34] and provide patients with an alternate, and most importantly, more effective, therapeutic option, I formed a new company, AOTI Inc., (Griffiths, 2011) with the intent to develop and ultimately patent the Topical Wound Oxygen innovation (Griffiths, et al., 2009). Invention patents are a finite work product that by their very patentability have gone through extensive peer review and are made openly available to the public via the USPTO website (United States Patent and Trademark Office, 2012).The resultant unique TWO_2 therapy product innovation addresses this global health need with simple to use devices that can be applied by the patient at home without the need for costly clinical caregivers. (Orsted, et al., 2012) The therapy has been shown to provide greater than 80% complete healing of these previously non-healing chronic ulcers with virtually no reoccurrences of the ulcers for up to three years. (Derk, 2011) (Sultan & Tawfick, 2010) (Blackman, et al., 2010). These resultant work products include the formation of new knowledge and an innovative technology as detailed in the product patent, clinical trial design, the products themselves and in the company structure that was put in place to implement them.

[34] Enormous in terms of both the clinical consequences/costs associated with them and also their epidemically growing prevalence worldwide

4.2.2.3. Was the innovation implemented effectively?

I drafted, submitted and achieved the required USA Food and Drug Administration (FDA) marketing clearance, the application and authorization being publicly available via FDA 510k website (FOOD AND DRUG ADMINISTRATION, 2012). The effective completion of product development and transfer of the innovation into manufacturing and release to sales is evidenced by the product datasheets (Griffiths, et al., 2012) and the company website. (Griffiths, et al., 2012). Successful Adoptance[35] of the innovation is also evidenced by this and the company's initial sales performance for the product detailed in the business plan utilized by the various stakeholders (Griffiths, 2011). The Innovation's adoptance is further demonstrated by the successful reimbursement for the therapy and the award of a federal contract within key US market segments, such as the Veterans Administration (VA) and other federal segments etc. (DEPARTMENT OF VETERANS AFFAIRS, 2009).

The clinical trial protocol that I drafted (Griffiths, 2009) demonstrates the innovation was not only developed and the required global regulatory approvals were achieved, such that an in-vivo randomized controlled patient trial could be conducted in order to provide evidence of greater efficacy for broader reimbursement, but also of successful implementation of the innovation[36], as feedback from the clinicians and users after initial adoptance of the innovation helped me define the desired treatment protocols and the primary and secondary end points for the trial. The trial protocol itself was peer reviewed by experts within the field and by a number of institutional review boards, was then published and made available to the public via USA Federal Government public access clinical trial website (clinicaltrials.gov, 2012).

Successful implementation and meaningful impact of the innovation is further demonstrated by the ever growing product sales shown in the business and strategic plan (Griffiths, 2011, p. 55) and expanding clinical utilization within the global healthcare community as evidenced by the ever growing number of clinical publications on an ever broader range of wound related clinical conditions, including such conditions as ; takayasu's arthritis (Kuspelo & Veikšina, 2011), venous stasis ulcers (Adler & Frye, 2012) (Sultan & Tawfick, 2010), septic forefoot Phlegmone (Adler & Frye, 2010), diabetic ulcers (Derk, 2011) (Blackman, et al., 2010), pressure ulcers (Kivelä, 2010) , complex

[35] Adoptance being the initial market use and acceptance.

[36] Klein and Knight (2005) define the difference between Adoption and Implementation as the former being that of the "*decision to use an innovation*" and contrastingly the later being ''*the transition period during which [individuals] ideally become increasingly skilful, consistent, and committed in their use of an innovation.*"

recalcitrant wounds in multi-morbid patients (Japour, et al., 2012) (Levine, 2011), to name a few. Another measurement of an innovative medical product's effective implementation within an intended market segment, as well as its acceptance within the clinical community as a whole, is that when the innovation is utilized into standard treatment regimes, that clinical evidence based practice guidelines and standards are developed by experts in the field, and such is the case with the recently published; 'Evidence-based practice standards for the use of topical pressurized oxygen therapy (TWO2)' (Orsted, et al., 2012).

The combination of the meaningfully improved clinical outcomes, the growing list of clinical indications, combined with the direct clinician and other stakeholder feedback, have also resulted in further product enhancements and product line extensions as detailed in the strategic plan (Griffiths, 2011) that epitomizes successful innovation implementation along the lines defined by Klein and Sorra (2005) and (1996), who describe *Implementation* as a process of achieving appropriate committed use of the *Innovation* by a primary target user and go on to further state that "I*t is the critical gateway between the decision to adopt an innovation and its routine use*" (1996, p. 1057).

4.2.2.4. Was the innovation implemented more effectively than is normal within the field?

4.2.2.4.1. Organizational and product implementation effectiveness

As mentioned in the introduction to this chapter, to address the question of whether these implemented innovations were implemented more effectively then commonly seen within the non-invasive medical device field, we will need to compare them against both industry norms and alternate treatment options. As discussed, in order to develop and bring this innovation to adoption and ultimately for it to be implemented fully within the wound care market, I had to establish a new company, AOTI Inc. utilizing the skills that I had learnt as an entrepreneur in forming and running my previous start-up entity eVent Medical Ltd. as summarized in my CV (Griffiths, 2012) and that will be discussed in more detail in the next section. In structuring this new company, I put in place a diversified and quasi-virtual organizational structure that by its very nature fostered innovation along the lines described by Malhotra in his book; Knowledge Management and Virtual Organizations (2000). As this author points out, just the creation and implementation of such an organizational structure and culture can be considered implementing innovation alone. Rather than building redundant and costly

departments to accomplish all the needed functions of the organization and to overcome the numerous barriers to entry outlined in the previous chapter, my approach was to bring on board a focused team of proven experts in the core competencies needed to be successful, and then outsource/contract-out the necessary ancillary support functions as detailed in my strategic plan for the company (Griffiths, 2011). This resulted in a truly global business that has cross-linked functions that utilize all the modern day communication tools available and an interactive management approach. I was able to hire the best candidates for their respective functions regardless of geographic location. This is evidenced by fact that our core business functions; R&D, Manufacturing, Regulatory & Quality, Sales, Marketing and Clinical Affairs, are managed by employees based in seven different countries and detailed on our website (AOTI Inc., 2012). The benefit of this decentralized model has been that that the company has attracted and retained some of the industry's best talent, allowing it to be very nimble and to react more effectively to the challenges encountered when fostering the innovation towards successful implementation[37]. The very nature of this business structure and approach has provided numerous efficiencies in all the business functions mentioned above, which is supported by the testimonials of numerous USA and International distribution and channel partners (USA and International Distributors, 2012). The ultimate result of which has been the successful global marketplace implementation of the Topical Wound Oxygen Therapy product line in less time and at far less cost than is normal within the industry.

In assessing this claim of effectiveness further, we need to first understand what are normal implementation times and costs within the non-invasive medical device field. In his presentation on Medical Device Development, Cittadine provides a good review of this area and explains that the commercialization timeline from early product development through regulatory approval is commonly 4 to 5 years and for small companies usually involves multiple rounds of financing totalling $10 million - $20 million (2010), and this does not include the time or cost required to achieve reimbursement in any significant market sector or geography. In the case of AOTI Inc., I was able to finance the company and the resultant Topical Wound Oxygen Therapy innovation development, including complete market release and initial reimbursement, solely through what is referred to as 'friends-and-family'[38] financing, and one Angel

[37] Core role driven and decentralized business models are imperative for success in the downturned economy we are faced with in which greater efficiency and effectiveness are key themes (Pigorini, et al., 2011)

[38] Friends and family refers to raising money intrinsically from the business proprietors and immediate associated parties.

investor[39] round. The total capital investment in the company to date is less than $5 million, $2 million of which came from one individual angel investor (Griffiths, 2011, p. 14). This funding approach was driven somewhat by the desire of the principles to maintain as much ownership of the company as possible, but primarily by the lack of any acceptable Institutional funding[40].

The importance of having achieved this implementation effectiveness with AOTI Inc. and having effectively done more with less is only amplified by the lack of small medical device company capitalization options available since the global financial market meltdown in 2008. In the last four years, the availability of capital within the medical device sector has swung 180 degrees, with less than 30% being made available now to smaller companies,[41] which is the complete opposite of conditions in 2007 (Ernst & Young, Global Life Science Center, 2011). Simply put, you have to already have money to be able to borrow or recapitalize within the sector. Ernst & Young's annual report on the state of the medical technology industry (2011) further elaborates on the incredibly difficult landscape that companies have faced in the last four years, which they describe as the "new normal", characterized by a radically changing; reimbursement, payment and regulatory environment, coupled with a significantly more challenging financing climate, that has all added up to put "Innovation at risk" (2011, p. 2). It can be summarised that the financial crisis not only dried up access to traditional capital routes for start-up companies within the industry, but has had profound impact on the ability of any medical device that is developed to get reimbursed and ultimately paid for by the healthcare systems that are in many cases being subjected to freefall austerity programmes.

Having successfully structured and funded an innovative company, AOTI Inc., which developed and implemented the Topical Wound Oxygen Therapy innovation within the global marketplace in less than half of the normal 4 to 5 years a timeframe (Kaplan, et al., 2004), (Combs, 2009), (Cittadine, 2010), (Makower, et al., 2010) and for between 25% and 50% of the cost that is normal within the industry (Shah, 2012), (Cittadine, 2010), (Espicom, 2012) as shown from our business model (Griffiths, 2011), but also under the additional global economic and financial constraints of the last four years, I believe is compelling evidence in support of the claim that implementation of this innovation was achieved more effectively than is normal within the non-invasive medical device field.

[39] Angel investor refers to an individual, not institutional, equity investor that does not take control or direct the management of the enterprise invested in.

[40] Institutional funding refers to traditional Venture Capital or Private Equity funding sources

[41] Less than $1 billion revenue

4.2.2.4.2. Regulatory and reimbursement implementation effectiveness

Espicom business intelligence points out that on average the regulatory approval timelines alone for non-invasive medical devices can range between two to seven years and costs approximately $2 million and $3 million for each major region sought; USA, Europe, Japan and China etc. (2012). The Topical Wound Oxygen therapy has not only achieved regulatory approval within the key segments, but within one year of attaining this prerequisite regulatory clearance has also achieved reimbursement within key market segments within the USA at a rate of approximately $3,300 per month of treatment (DEPARTMENT OF VETERANS AFFAIRS, 2009) and for no additional cost over that already outlined in the previous paragraph, which again supports the assertion that my implementation of this innovation was achieved more effectively than is normal.

4.2.2.4.3. Clinical outcomes and healthcare cost saving implementation effectiveness

Worldwide, the direct reimbursement of all medical devices only accounts for about 5% of total healthcare spending compared to 70% for personnel and hospital organization costs (Espicom Health-care Intelligence, 2011). In the USA alone over $25 billion is spent annually on just the ongoing maintenance of chronic wounds (Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, 2012), which equates to an average of about $4,400 per wound per year (Landers, 2008). Even at the $3,300 per month treatment cost, the successful implementation of this innovation does not significantly add to the cost of care, but to the contrary, should over time significantly decrease the ongoing costs of care for these patients. This will be achieved by a combination of the therapy's ability to be utilized at home by the patient without the need for costly caregivers as described above, but also due to its ability to heal chronic wounds at between two to three times the rate and with much lower reoccurrence than with other treatment options[42]. Therefore, and as is supported by numerous physician testimonials (Frykberg, et al., 2012), each wound healed by this therapy would remove its annual ongoing cost burden, not to mention the improvements in morbidity, mortality and quality of life for the patients themselves[43]. Derk emphasizes this point in his paper on the topic, where he identifies the direct

[42] The Innovation ($TWO_{2)}$ has been shown to completely heal chronic wounds at a greater than 80% rate at 12 weeks compared to the between 30% and 40% rate of other therapeutic modalities (Derk, 2011) (Sultan & Tawfick, 2010) (Blackman, et al., 2010)

[43] 39% to 80% of diabetic ulcer amputees will either die or have a second amputation within 5 years (Moulik, et al., 2003) and over 30% will either die or have a second amputation within 2 years (Bruttocao, et al., 2011)

savings that TWO_2 therapy provides, while achieving far greater healing outcomes at less than half the applied costs of the best alternate modalities (2011).

When assessing the economic cost-effectiveness of an invention, one approach is to calculate the cost per incremental Quality Adjusted Life Years (QALY) and this is commonly used by payers as justification to pay for the innovation or treatment, a figure of $50,000 of incremental cost due to the intervention per QALY is a threshold often used in the USA and in the United Kingdom; NICE[44] utilizes a value of about $45,000. (Steinbrook, 2008). QALY simply means a year of life lived in perfect health, so for someone with a disease that is not in perfect health you would modify this by a utility value, for instance for a patient with a non infected diabetic ulcer a utility factor of 0.75 is commonly used (Whitehead, et al., 2011), meaning that the cost of the intervention for 16 months would need to be below the thresholds amount detailed above to be deemed cost-effective. So to calculate the cost effectiveness of TWO_2 therapy we should first look at the total therapeutic costs to heal an ulcer and then the length of ulcer closure. The reimbursed cost for the therapy in the USA is $3,300 per month and an average conservative time to complete closure of a chronic ulcer as demonstrated in various publications is three months, so the total incremental cost of the innovation to heal a wound is approximately $9,900 (Derk, 2011). Clinical studies indicate that these ulcers remain closed for at least 3 years post closure (Blackman, et al., 2010) (Sultan & Tawfick, 2010). Therefore the cost per QALY is; $9,900 / 3 years X 0.75 utility factor = $2,475 per QALY. If we compare this to the cost per QALY of other alternate therapeutic modalities; $27,310 for Full Body HBO (Chow, et al., 2008), €24 881 for Negative Pressure Wound Therapy (Whitehead, et al., 2011) , which have lower efficacy (closure) rates and much greater reoccurrence rates (WILD, et al., 2010) (Cavanagh, et al., 2005), we see that TWO_2 is far more cost-effective than these alternate therapeutics.

Utilizing the proven positive impact on healthcare outcomes, cost of care reduction and the potential for the innovation to save the healthcare system millions of dollars over time as it is utilized, further supports the notion that this innovation not only has, but should continue to have, significant positive impact in the wound care arena and that its implementation being far more effective than is normal for therapeutic products within the field.

[44] National Institute for Clinical Excellence (NICE)

4.2.2.4.4. Ethical implementation effectiveness

The issue of ethics commonly comes up in healthcare, but is normally focused around clinical aspects and end of life decisions (Fox, et al., 2010). Over the last fifty years, the increasing life expectancy associated with better medical treatments and the resultant growing aging population driven by the baby boom generation,[45] [46] and the associated increases in people with chronic conditions, such as; diabetes and respiratory disease etc., has together created an enormous increase in the amount that countries spend on healthcare. In the USA an incredible $2.6 Trillion or $8,400 per capita, that equates to 18% of Gross domestic product (GDP), was spent on healthcare in 2010 and other westernized countries are not that far behind these ratios (Organisation for Economic Co-operation and Development , 2011). This demographic ticking time bomb coupled with an ever increasing array of treatment options, and the availability of new technologies and drugs, is part of the explanation for these spiralling costs. When you add into the mix the austere economic realities that world economies have faced since the 2008 economic downturn (Ernst & Young, Global Life Science Center, 2011), it's clear that hard decisions need to be made as to where every healthcare dollar, or Euro, is spent. This raises an ethical dilemma for societies as to what care to fund and for whom. It also reinforces the premise that new healthcare innovations should address not purely clinical needs, but do so while offering an economic benefit, be it by lower cost of treatments or by an overall reduction in cost of care for the patient over time, something that my innovations under discussion have clearly achieved.

One approach to help standardize care and rein-in costs, which has grown into a gold standard over the last decade, has been that of evidence based medicine, whereby the decisions to use and pay for a therapeutic modality is driven by empirical peer reviewed clinical evidence and not by historical practice standards or physician preferences (Mauck & Timmermans, 2005). This approach has standardized the care available to patients in many cases, not by necessarily convincing the treating physicians that an alternate treatment is not warranted, but by simply not funding modalities that do not reach the evidence based bar. Belsey et al. emphasize this point in their report on the subject, concluding that evidence based medicine since its emergence 15 years ago "have seen its adoption, alongside health economics, as the gold standard tool for commissioning and provision of health services, both in the UK and around the world"

[45] The baby boom generation are those that were born after the 2nd world war and are reaching 65 years of age beginning now

[46] The numbers of persons 65 years or older are expected to double by 2030 and similarly grow in the EU and Japan (Administration on Aging, 2011).

(2009, p. 8). The problem with this system has been that this newer barrier to entry has only generally been applied to new therapeutics and not retrospectively to older ones that in many cases were just "grandfathered-in",[47] this has resulted in a dichotomy of what is, and what isn't, reimbursed. Another major limitation of this approach is that even after jumping through all the hoops needed to gain regulatory clearance for a new innovation in each respective region around the globe, companies are then additionally required to provide unequivocal clinical evidence of measurably improved clinical outcomes to the various separate reimbursement bodies globally, in order for the new therapeutic to be funded and paid for. This by its very nature requires a company to conduct at least one, if not multiple, randomized prospective controlled clinical trials that show statistically significant[48] improved clinical outcomes compared to existing standards of care. In the non-invasive medical device field these trials are not commonly required for regulatory approvals, so this becomes an additional and very significant hurdle for any small company to overcome (Kramer & Schulman, 2012), and which I elaborated on in greater detail in the previous chapter on barriers to entry.

The main ethical dilemma that I believe has evolved as evidence based medicine has become the de-facto norm enforced rigorously by payers globally, is that many promising life-enhancing and potentially life-saving innovations never become available to the majority of patients that could benefit from them, as the companies that have developed them tend to be small and are unable to overcome this evidence based bar, either due to inadequate financing or/and clinical trial knowledge, so therefore fail to gain reimbursement for their therapeutic and thus never implement the innovation fully into the marketplace, thereby depriving patients of potentially life altering treatments. It's ironic that the acronym for the reimbursement body tasked with making coverage decision in the United Kingdom is 'NICE',[49] as it clearly has a reputation for commonly saying 'no' and turning down coverage for new treatment modalities. (Steinbrook, 2008) Conversely, many larger companies, particularly drug and invasive device companies, where the costs of trials are far greater than those needed for non-invasive devices (Bollyky, et al., 2010), commonly decide for pure economic return on investment reasons not to pursue the innovation through all these stages of implementation, irrespective of the clinical impact it may have on the intended population, again

[47] Grandfathered in means they retained their historical reimbursement and were not assessed to the new benchmark level

[48] Clinical trials used for reimbursement or regulatory clearance, must be well structured and randomized and their outcomes must meet minimal levels of statistical significance in order to be considered under evidence based medicine empirics.

[49] National Institute for Clinical Excellence (NICE)

depriving patients of potentially life altering treatments purely due to economic return reasons.

As mentioned earlier, one approach companies utilize to help combat the high cost of randomized clinical trials, is to select less expensive countries to conduct these trials. This raises the question of whether this is ethical. In the cases of non-invasive medical devices, which are the focus of this thesis, these devices have already received the required regulatory approvals to be marketed and these trials are required solely to attain broader reimbursement. Therefore, as long as the devices that are the subject of the trial are available for use within the trial country, then this approach is completely ethical, as it only allows for broader potential access to the device within that market and others. Another complimentary approach is to gather clinical and health economic data from utilization of the approved device within organisations where reimbursement can be attained without randomized clinical trials, referred to as registry data. Again, as before, this approach is completely ethical as it supports observational clinical evidence gathering during therapeutic utilization within the afflicted patient population.

I believe strongly that healthcare payers, be them public or private, and the healthcare companies that develop new innovations, both share in the responsibility of implementing clinically significant treatment modalities into their intended market segments as effectively as possible, so that the as many patients as possible can benefit from their outcomes. This is both an ethical and a social responsibility and ultimately should result in good financial return for the business as well. Ethics and business success are by no means mutually exclusive of each other. With this mindset, I have focused my current company on helping get the Topical Wound Oxygen therapy out to as many patients globally as quickly as possible such that we can save their limbs and sometimes their lives as well. Due to our efficient attainment of reimbursement already in key needy sectors of the USA chronic wound market, our therapy today has already been utilized to heal the wounds in over 1,000 patients[50] in the USA alone and probably twice this amount globally as is supported by the figures in the strategic business plan. (Griffiths, 2011, p. 4) To help further support the ethical application of resources and logical efficiencies of care, I have also tried to get the message out and have presented and spoken at a number of conferences globally over the last five years as detailed in my CV and conference presentations (Griffiths, 2012), attempting to educate the healthcare community on the plights of chronic wound patients and the costs they impose on their healthcare systems, as well as the therapeutic options that are open to heal them.

[50] Calculated from the prescription orders for the therapy within the USA and number of treatments and the duration of therapy provided

4.2.3. Inspiration [51] Ventilator Product Family and eVent Medical Ltd.

Innovation	Global Health Need Addressed	Evidenced within/by Public Work
Inspiration Ventilator Product Family eVent Medical Ltd. Company	Need for Life Support Intensive Care ventilation that is more affordable and flexible to operate in the less developed countries and harsh environments encountered around the world.	Inspiration ventilator patent (Griffiths & Daescher, 2006) Inspiration ventilator FDA 510 (k) marketing application and clearance (Food and Drug Administration, 2002) eVent Medical Ltd. Strategic Business Plan (Griffiths, 2005) Entrepreneurial Company structure newspaper article (Lytle, 2005) eVent Medical Ltd. Quality System (Griffiths, 2001)

4.2.3.1. Which global health need was addressed?

This earlier implemented innovation of mine is another public works example of an innovation that was implemented more effectively than is normal within the non-invasive medical device field, the difference being in this case that it is in the Respiratory Care, and more explicitly the Intensive Care Ventilator, market segment, opposed to the Wound Care market segment for the previous example. The innovation and its effectiveness in the marketplace was not only significant back when it was released, but is still evident today as supported by the product line and the company's continued success as demonstrated on its website (eVent Medical Inc., 2012).

In this market it was clear that there was a need for a low cost and effective life support intensive care ventilator that was more affordable and flexible to operate in the less developed countries and the harsh environments encountered around the world. According to NCIIA[52] millions of people die each year in developing countries from lack of access to ventilators; additionally, the U.S. has only 14% of the ventilators needed in the event of an influenza epidemic (2010). Marketstrat in their global ventilator market

[51] Inspiration is a registered Trademark of eVent Medical Inc.
[52] NCIIA is the National Collegiate Inventors and Innovators Alliance

report points out that developing countries have an ever increasing demand for capable ventilators due to evolving healthcare systems, extensive medical facility building and greater prosperity (Marketstrat, Inc., 2011). Historically, the Intensive Care Units (ICU) ventilator market had been dominated by one of three major players; Puritan Bennett from the United States, Draeger and Gettinge (formerly Siemens) from Europe, and a multitude of smaller regional companies. Per the primary market research that I conducted as that is incorporated within the eVent Medical Ltd. Strategic Business Plan, the user cost of ICU high performance ventilators ranged on average between $27,000 and $35,000 (Griffiths, 2005) and more recently Husseini reported that the average ICU ventilator cost was approximately $30,000 (2010, p. 2). Due to these high prices coupled with the requirement for these high performing products to have stable electrical and pneumatic gas sources, not commonly seen outside of the western world, these clinically needed ventilation modalities and performance capabilities were in many cases beyond the reach[53] of many developing markets, despite their growing need.

4.2.3.2. What was the innovation that addressed this need?

Within my eVent Medical Business Plan public works I detailed the Inspiration ventilator's unique design, with it incorporating a 'solid state pneumatics[54]' and 'internal battery driven compressor, and web-based monitoring (Mini-Web) technology' (2005, pp. 3-5). These design features made the ventilator very compact, robust and also allowed it to operate independent of stable gas and electrical supplies. The product was also very easy to operate with an integral graphical user interface. The importance of enhanced and easier to use graphical interfaces, such as was provided by the mini web server web-based monitoring in this product, has still eluded many ventilator manufacturers to this day, as Seiver pointed out in his discussion on ventilation trends, in stating that; "a familiar, information-rich, insanely great interface" is something that most ventilator companies should still be looking to engineer. (2009, p. 54)

4.2.3.3. Was the innovation implemented effectively?

I founded eVent Medical Ltd. with the intent to develop and implement into the market a unique low cost high performance ventilator technology, as there was, and still is, a clear need for a life support (ICU) ventilator that is more affordable and flexible to operate, especially in the less developed countries and harsh environments around the

[53] Both financially and infrastructure support wise

[54] Solid state refers to a solid block where all the valves were mounted and gas pathways were channelled within, opposed to traditional "spaghetti' type tubing seen in most ventilators. This made the product very robust and extremely compact.

world. The Inspiration is a low cost flexible ICU ventilator that incorporates many high end clinical features, integral gas supply and revolutionary remote monitoring and control capabilities via an embedded mini-web server. Formation of new knowledge through the product's innovative technology is detailed in my public works product patent (Griffiths & Daescher, 2006) and by this very nature in the products themselves. The patent was peer reviewed by experts, published and made available to the public via publications as evidenced by the USPTO public database (United States Patent and Trademark Office, 2012). I then drafted and submitted the application and achieved United States marketing clearance authorization (Food and Drug Administration, 2002) this is publicly available via the Food and Drug Administration clearance database website (FOOD AND DRUG ADMINISTRATION, 2012)

My public works eVent Medical strategic business plan (Griffiths, 2005) illustrates the entrepreneurial company structure that I established and which also acted as the roadmap for all stakeholders for the company and innovation development. This plan was reviewed, lived by and involved many stakeholders. The innovativeness of my approach is further supported by a newspaper article on me and the company written at that time (Lytle, 2005).

The formation of an innovative company structure and product through the development cycle is evidenced by the eVent Medical Quality system and resultant Quality Manual (Griffiths, 2001) that met audit scrutiny and criteria for both USA-FDA and European-CE regulatory agencies quality system approvals. The effective completion of product development into manufacturing and release to sales is evidences by the Product datasheets (Griffiths, 2002)and the marketing clearance by the FDA in the USA. Successful Adoptance of the innovation is also evidenced by this and also the company's initial sales performance for the product as detailed in its strategic plan (Griffiths, 2005, p. 37). Successful Implementation of the innovation is evidenced by the continued sales of the Inspiration product line over the last ten years, with the last five being under the Kobayashi umbrella (Kobayashi Pharmaceutical, Ltd. , 2007) (Kobayashi Pharmaceutical, Ltd., 2010). Additionally, successful implementation is also evidenced by the number of new product line extension based around this core innovative technology platform that have been brought to market, as shown on the company's current website. (eVent Medical Inc., 2012)

4.2.3.4. Was the innovation implemented more effectively than is normal in the field?

4.2.3.4.1. Organization and product implementation effectiveness

When I formed eVent Medical Ltd. it was my first start-up venture, having previously worked for various conglomerates and corporations within the medical device field. In similar vein to my second start-up entity, AOTI Inc, described above, but at that time with far less knowledge and experience, I put in place a flexible diversified and quasi-virtual organizational structure that allowed me to attract away from their corporate employers and bring on board proven experts in the core competencies needed to be successful. Unlike AOTI Inc., which was formed as an American company, eVent Medical Ltd. was incorporated in Galway, Ireland, in order to take advantage of the experienced ventilator manufacturing expertise that existed in the area and also to focus initially on CE mark approval that would provided the fastest required regulatory clearances to market the product to the intended market segments, namely; the lesser developed markets of globe. I then outsourced/contracted-out all the necessary ancillary support functions, as detailed in my strategic plan for the company (Griffiths, 2005).

The company was formed with the intent to develop a new innovative intensive care ventilator based on core technology that I had envisioned from an early prototype concept that I had seen and that I believed could provide high end features with added flexibility and at a far lower cost than other products within the industry. This concept of developing products with the end market customer's needs at the forefront, but also with the cost of purchase, ownership and operation being a driving factor, has been termed 'Design to Value'as illustrated in Figure 5 below and as has been extensively elaborated on recently by Chilukuri and colleagues in their report titled 'Design to value in medical devices' and who go as far as to say that "*As price pressures increase, medical device makers need to rethink product development processes"* and *"If medical device companies want to continue to make money as prices face continued pressure, their only option is to take cost out."* (2010, p. 1). This approach is one that I employed when starting eVent Medical over a decade ago and has proven to be paramount to the success of the Inspiration product line innovations ever since.

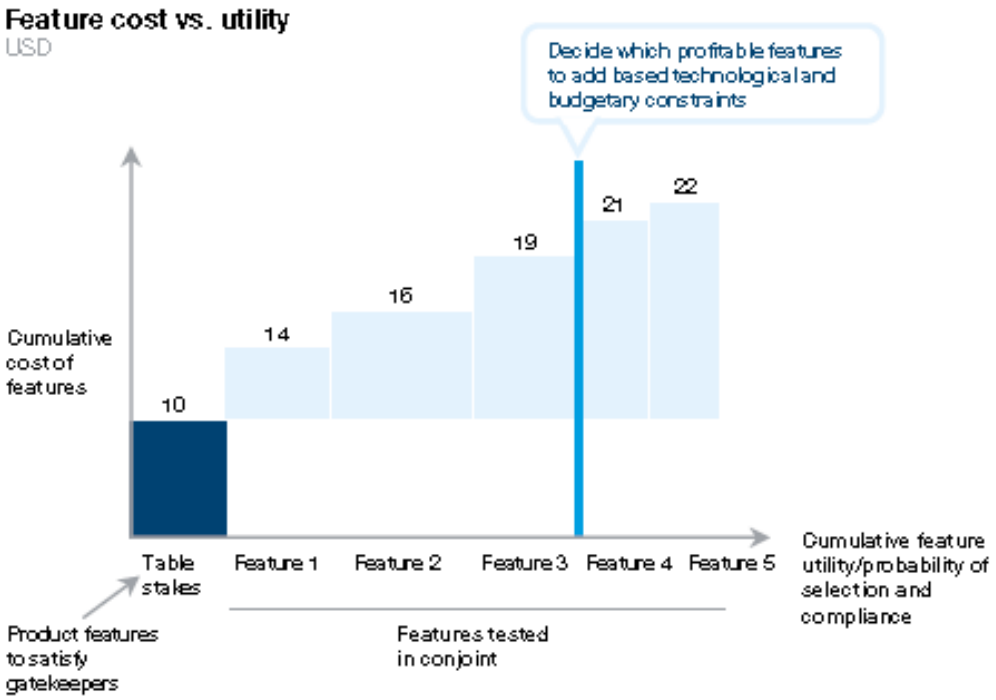

Figure 5: Conjoint analyses from Design to value in medical devices (Chilukuri, et al., 2010)

As the eVent Medical Ltd. Strategic Business Plan details, the resultant Inspiration ventilator family was developed and brought to market in less than three years and for a total capital investment of only 3 million dollars, which in this case was funded solely by friends-and-family financing[55] and one distribution channel partner. (Griffiths, 2005) If we compare these cost to market implementation figures to those from the publications of (Makower, et al., 2010), Cittadine (2010), (Shah, 2012) and Ernst & Young (2011), that are related to industry norms for development timelines and capital investments. It is evident that I was successful in forming and funding eVent Medical; Ltd.., and then developed and implemented the Inspiration ventilator product line within the global marketplace, in less than half the time and for about a quarter of the cost that is normal within the industry, evidencing that my implementation of this innovation was also achieved more efficiently than is normal within the field.

4.2.3.4.2. Clinical outcomes and healthcare cost saving implementation effectiveness

The Inspiration ventilator had meaningful impact on the intended ventilated patient market in that it provided extensive high end clinical features and added flexibility at as

[55] Friends and family refers to raising money intrinsically from the business proprietors and immediate associated parties.

low as half the price of other products, thereby not only lowering traditional equipment costs, but also making the devices more economically viable in less developed markets and countries. This effect is clearly demonstrated in the eVent Medical Strategic Plan by the sales mix of products being distributed throughout the globe and with many sales into the lesser developed market segments (Griffiths, 2005, p. 26).

The chart below from my eVent Medical Strategic Plan (Griffiths, 2005) illustrates the Price to Performance positioning of the Inspiration ventilators relative to competitive products in the marketplace at that time. As you can see, the Inspiration offered significant high-end performance capabilities at a price point of far lesser performing products, in most cases for as little as one third of the price of the leading brands.

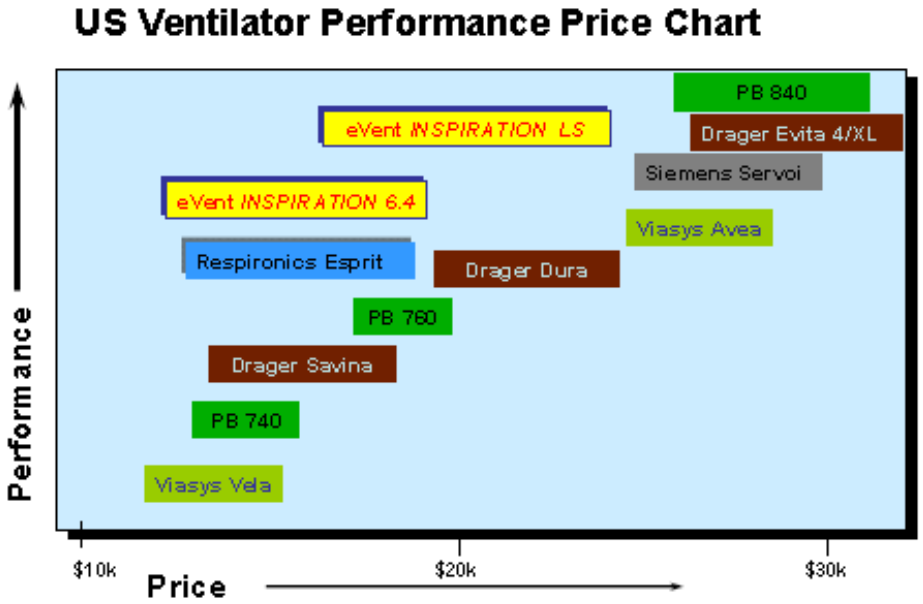

Figure 6. Inspiration Ventilator Price vs Performance from Staregic Plan Public Works Page 24

The average price point for a high performance ICU ventilator in the USA was estimated recently still to be approximately $30,000 (Al Husseini, et al., 2010) demonstrating that there has been no meaningful price erosion over the last 5 years and supporting the continued sales and relevance of the impact of this innovation within the market place.

Two additional unique feature of the patented electro-pneumatic[56] design of the Inspiration ventilator are its ability to utilize a novel gas named Heliox, which is a

[56] Electro-pneumatic refers to the integration of the control and delivery of the gases utilized for breathing (commonly air and oxygen) with the electronic components and circuitry needed to control and monitor their safe delivery and the patient's response to their delivery.

mixture of Helium and Oxygen, that that allows for easier ventilation of obstructed breathing airways and can facilitate weaning[57] patients off the ventilator much quicker (Flynn, et al., 2010), (Venkataraman, 2006) and its ability to provide this within non-invasive ventilation modes[58]. Dasta demonstrated that the incremental cost associated with ventilating a patient in an intensive care unit within the USA was $1,522 per day, and he summates that "Interventions that result in reduced intensive care unit length of stay and/or duration of mechanical ventilation could lead to substantial reductions in total inpatient cost" (2005, p. 1270). Therefore the capability of the Inspiration to help wean patients off the ventilator quicker provides additional operational cost savings to the healthcare community to those related directly to its lower purchase price. Extrapolating these savings out shows that based on a mid-range average sales price of the Inspiration ventilator of $10,000, that its total acquisition price could be offset entirely by just six patient ventilation days saved. This could be as one patient weaning of the ventilator six days earlier, or six patients each weaning one day earlier, or anything in-between.

Combined, the continued market presence and success of the Inspiration innovation within the marketplace, the significant direct cost savings it provides related to its much lower purchase price and to the weaning reduction cost savings it can furnish, I believe strongly supports the concept that from a Clinical Outcomes and Healthcare Cost Saving standpoint that the innovation was implemented more effectively than is normal for products within the ICU ventilator marketplace.

[57] Weaning in this case refers to the to the methodical sequential reduction in mechanical ventilator support of a patient's breathing and the corresponding pick p in the patient's breathing workload

[58] Non-invasive ventilation is ventilating patient via s mask or nasal prong, opposed to invasive ventilation, that involves inserting a tracheal tube into the patients airways or by creating a tracheotomy

4.2.4. 7250 Metabolic Monitor

Innovation	Global Health Need Addressed	Evidenced within/by Public Work
7250 Metabolic Monitor	Inaccurate measurements of metabolic demands/needs of ventilated patients within Intensive Care Units result in dangerous under feeding, overfeeding or imbalanced substrates.	Technical Metabolic Monitor Handbook (Griffiths, 1996) Clinical Metabolic Monitor Handbook (Griffiths, 1996)

My involvement in the market development and management of the 7250 Metabolic monitor was one of my earliest examples of implementing an innovation into the Respiratory care field. In this case it was the stewardship as the product manager of an innovative product for which I was responsible within a multi-national corporation.

4.2.4.1. Which global health need was addressed?

Inaccurate measurements of metabolic demands/needs[59] of ventilated patients within Intensive Care Units results in dangerous; under feeding, overfeeding or imbalanced substrates[60], resulting is extended ventilation days and costs, or more serious clinical outcomes. (Faisy, et al., 2003). Historical metabolic monitors had been ineffective and inaccurate in ventilated patients. The problem was these measurement were inherently difficult to obtain and the values taken on a spot check bases did not track true metabolism as the patient's clinical condition varied over time, resulting commonly in dangerous overfeeding, underfeeding and inadequate ventilator support.

4.2.4.2. What was the innovation that addressed this need?

The unique technology provided easy real-time continuous measurements of these previously described parameters, and along with that with an entered urine urea value (representing nitrogen metabolism) the actual breakdown of substrate metabolism for the patient. This provided unheralded accuracy in the adjustment of the nutritional

[59] Metabolic monitoring traditionally refers to a spot-check measurement of a patient's Oxygen Consumption (VO_2) and Carbon Dioxide production (VCO_2)production, which when divided by each other gives you the Respiratory Quotient (RQ) and can be used to calculate the total Resting Energy Expenditure (REE), which is a measurement of total caloric needs.

[60] Substrates being the mix of Protein Fat and Carbohydrates the body metabolizes

support of the ventilated patient in terms of total caloric needs and substrate mix, as well as appropriate ventilator settings management

The 7250 Metabolic Monitor significantly improved how many ventilated patients are metabolically managed by proving accurate measurements of the patient's nutritional needs and metabolic work rate. This allowed clinicians to accurately tailor therapy to these needs, opposed to just utilizing inaccurate predictive equations. The public works examples; technical (Griffiths, 1996) and clinical handbooks (Griffiths, 1996), were instrumental in educating clinicians and biomedical engineers as to the problem associated with traditional measurement techniques and how this new innovative technology overcame such issues, it also outlined how to interpret and utilize this new information.

4.2.4.3. Was the innovation implemented more effectively than is normal in the field?

The Clinical (Griffiths, 1996) and Technical (Griffiths, 1996) metabolic handbooks were written and made freely available to the respiratory care profession and disseminated new knowledge, ideas and clinical approaches to the field. The detailed research, new concepts and resultant metabolic product development outlined in these texts supported the adoptance into the ventilator market place of the 7250 metabolic monitor. This adoption resulted in improved patient care and outcomes in a growing number of clinical conditions Successful and meaningful Implementation of the innovation is evidenced in its continued utilization over the last fifteen years across a widening gambit of conditions, as demonstrated in numerous published clinical papers citing its use over the last decade; (Reid, 2007) (Faisy, et al., 2003), (Miwa, et al., 2003). (Brandi, et al., 1999), (Barco, et al., 1998)

This innovation was developed while I worked for a corporation and was therefore one development project amongst many that this medium sized ($300 million annual revenue) company had ongoing at the time. Like is common with many product development projects, this project was assessed at various stages of development as to its continued viability. This assessment was based around the potential return on investment to the company and other strategic initiatives the company had at that time and which over the course of the development changed significantly. Despite all this and the declining financial position of the company, which caused the development team to be downsized on numerous occasions, the 7250 metabolic monitor was developed and released to the marketplace in less than four years and due to its small,

but dedicated and focused development team, for a minimal amount of capital expense allocation from the corporation. When this is compared to the timeline and cost norms for the industry established earlier, they support the claim that the implementation of this innovation was also achieved more efficiently than is normal within the field.

4.3. Summary of the overall impact of the implementation of innovation from my public works

In the previous section of this chapter I have conducted a detailed evaluation and analysis of three of my public works that I believe best validate my claim of making *unique contributions* that have had *significant impact* within my area of expertise and that show specifically that I have *implemented Innovation more effectively within the highly regulated non-invasive medical device field.* However, as I have detailed throughout this context statement, my public works as a whole encompasses more than just these three examples. Therefore, it is pertinent I believe to synthesize my public works in their entirety in order to assess how they support my claim and the overall contributions that I have made to the sector.

Progressively throughout my career within this specialized sector, I have directly engaged in advanced work based learning that has taken many forms that has been interdisciplinary in nature. The impact of this on my professional development is summarized within my detailed CV (Griffiths, 2012) and highlights my increasing professional responsibilities, career evolution, expanding academic and clinical credentials and extensive history of lecturing and speaking engagements. These varied roles have required me to analyze and overcome numerous complex problems, many of which have been unforeseen, and conceptualize multiple work-based projects that have required extensive methodological research, that have resulted in new ideas, new approaches and my cited public work results. Examples of which include my three public works explored in great detail in the section above. This impact is also further supported by the day to day operation and strategic stewardship of the companies, eVent Medical Ltd. and AOTI Inc., that I formed and ran within the sector and which continue to thrive today, despite all the economic turmoil we have faced in the last decade, and as evidenced by their company webs sites (AOTI Inc., 2012) (Griffiths, et al., 2012) and annual reports (Kobayashi Pharmaceutical, Ltd., 2010) and by our dealer testimonials (USA and International Distributors, 2012). I have contributed an array of work related projects that have been quite varied in nature, but that in many cases have added new knowledge to the field. I have been an advanced educator, having conducting numerous presentations globally, and have developed a number of new educational materials and

manuals as demonstrated by my public works conference presentations (Griffiths, 1995 - 2012) and pre-study manuals (Griffiths & Canfield, 1993) etc. I have been an Inventor, developing a number of new technologies as evidenced by my patents in both the ventilator (Griffiths & Daescher, 2006) and wound care (Griffiths, et al., 2009) arenas. I have also been an entrepreneurial company founder and operational executive, as supported by my various company strategic plans for both eVent Medical Ltd. (Griffiths, 2005) and AOTI Inc. (Griffiths, 2011), as well as in local newspaper articles (Lytle, 2005) and press releases (Doyle, 2010).

Additionally, these combined public works outputs not only demonstrate attainment of my claim, but also how I have utilized my learning in daily practice and have contributed to my field of expertise, that when combined with the learning and gained expertise that I have attained over two and a half decades, has furthered my standing within the industry and allowed me to be viewed as a subject matter expert by my peers, which is evidenced within my detailed CV (Griffiths, 2012) by my varied speaking engagements, professional society memberships and fellow designation.

Throughout all of these endeavours there is a common thread that I believe solidifies my contributions, being that I have focused on implementing meaningful product innovations[61] and creating business structures that are more effective than is normal within this sector. By this I mean that I have identified, developed, and invented products that address real world needs, with an awareness of the ethical and economic dilemmas that we face in the healthcare community today. This requires focusing not solely on the clinical benefits of the innovations, but also on their overall economic impact and the benefits they purport to bring to the healthcare system as a whole. I have achieved this outcome by forming new entrepreneurially structured entities that have implemented these innovations into the global market place faster and for far less cost than is the norm for the sector, all of which is evidenced again by my three public works products detailed previously in this chapter associated with; the Topical Wound Oxygen Therapy and AOTI Inc. (Griffiths, 2011), the Inspiration Ventilator product line and eVent Medical Ltd. (Griffiths, 2005), and the 7250 Metabolic monitor (Griffiths, 1996). Within each of these different public works examples I have demonstrated more effective implementation in a number of the required aspects, including those of; organizational structure, regulatory approval and reimbursement attainment, product and clinical outcomes, and healthcare system cost saving.

[61] These include technological product innovations as are detailed in the earlier sections of this chapter, but also educational and methodological innovations as discussed throughout the thesis.

I believe that the single most significant legacy related to my claim is that associated with the positive clinical-economic healthcare impact that the Topical Wound Oxygen Therapy product line has and will continue to provide to global healthcare systems. Clinically, this implemented innovation has been demonstrated to completely heal recalcitrant ulcers at unprecedented efficacy ratios of greater than 80%, as evidenced by numerous published clinical studies (Frykberg, et al., 2012), (Japour, et al., 2012), (Sultan & Tawfick, 2010), (Blackman, et al., 2010) to cite a few. Economically, and as I have detailed earlier in this chapter, this therapy achieves these clinical outcomes for far less applied cost than any other therapeutic modality of far lower efficacy. When combined with the incredibly low wound reoccurrences also evidenced in these clinical trials, the ultimate result will be significantly reduced ongoing healthcare costs associated with these chronic epidemically growing conditions.

4.4. Pragmatic Entrepreneurship and Best Practice recommendations

The pragmatic entrepreneurship approach that I have refined over two decades as a practitioner within my field of expertise and which I have elaborated on within the preceding discussions about my public works, provides insight into some best practice recommendations that may be useful to others within the medical device field and in other industries as well. My approach and model is contingent on a number of iterative but interdependent phases that grow on each other and that are intended to allow for faster transition through the various stages of implementation for the innovation, these can be summarized by the stages and in the diagram that follow:

1. This initial grounding phase is identifying and understanding a clear proven user/market need that is underserved by existing solutions.

2. This need then directs the focused development of innovative solutions, be them completely new ideas, or a modification of existing ideas or technology.

3. The next step is the establishment of a lean organizational structure capable of implementing the innovation. The focus here must be on talent and expertise and not location, with careful selection of trusted, known, competent individuals for the core functional areas required and that can work independently.

4. Where possible, outsource expensive infrastructure such as manufacturing to experts in the respective activity, but always provide management oversight of these critical functions to guarantee quality, as this minimizes capital needs and

more effectively achieves scalability as the business grows.

5. The regulatory and follow on marketing strategy should focus on the development of all global markets in parallel, in order to maximize both the business opportunity, ethical clinical impact and to provide revenue earlier.

6. Throughout the stages always reassess progress and adapt to changing regulatory and reimbursement landscapes and changing market needs.

7. Where possible align raising funds to minimize dilution. Exploit easier and more accessible funding, such as friends and family and angel investors, rather than larger time-consuming and more dilutive venture capital rounds. Do not underestimate capital raising time requirements and complexities.

Figure 7. Pragmatic Entrepreneurship Model

To effectively utilize this model it is critical that the entrepreneurial leader have the skills to both manage and motivate geographically dispersed team members. This should include minimal but adequate reporting structures, clear dissemination and buy-in to the strategic vision for the entity, and where possible, performance based equity type compensation. The importance of these facets should not be underestimated if the venture is to be a success.

5. Conclusions and Reflections

As I have outlined in the preceding sections, I am an established industry professional that has progressively attained greater levels of responsibility and professional standing over a long career in the medical device industry. My body of public works is a combination of pertinent examples from this period, that I believe when assessed in their entirety demonstrate that I have not only contributed to, but have significantly affected, daily practice by implementing innovation more effectively within the non-invasive medical devices field.

I have repeatedly engaged directly in advanced work based learning that has taken many forms and that has been clearly interdisciplinary in nature. Although, there has been one common theme, that being the medical device industry, and more specifically, the Respiratory and Wound Care segments of that industry. I have been an advanced educator, an inventor, a product developer, a product and marketing manager, an operational executive and an entrepreneurial company founder, all within this specialized sector. These varied roles have required me to analyze and overcome a considerable number of complex problems and obstacles, many of which have been unforeseen, requiring me to conceptualize multiple work based projects involving extensive methodological research, that in many cases have resulted in new ideas and new approaches as evidenced by the public work examples summarized within this context statement. The outputs of these projects have been quite varied, but have in many cases added new knowledge to the field, but uniformly have incorporated a tangible real world context and work based aspect.

Overcoming the many varied obstacles that I have encountered over the years has necessitated the development of a unique set of skills, encompassing the many technological, clinical and management aspects of my profession. In honing these skills, it has taught me to evolve my approach in analyzing and addressing challenges by calling on my work based learning and the life lessons learnt. As I have become more experienced in implementing innovation, I have developed a very pragmatic approach to problem solving that always includes a real world needs assessment sanity check, which allows me to clearly envision innovative solutions and create unique organizational structures to implement them more effectively. The learning and gained expertise attained through this iterative process has also allowed me to reach the highest leadership level within my profession and to be viewed as a subject matter expert by many of my peers.

Within the preceding chapter I have focused my analysis of my public works to three prominent examples of technological innovations addressing distinct real world global health needs that I implemented more effectively and utilizing innovative organizational structures and which I believe best illustrate my claim. However, additionally throughout my context statement I have touched on numerous other public works examples that demonstrate my accumulative workplace driven knowledge attainment, its impartment and the resultant impact to my field of expertise in the many professional areas that I have had the privilege to practice and contribute These include such areas as; teaching and education, subject matter presentations, organizational leadership and pragmatic entrepreneurship, admittedly them likely being less impactful individually to my specific claim than those public works examples that I focused on in my analysis. When combined though, these works demonstrate a continuous theme that I have had significant impact in both my professional development and the efficacy of my professional standing. This body of public works in its entirety also demonstrates how I have utilized my learning in daily practice and how I have contributed significantly to my field of expertise with advanced new innovations and knowledge and specifically demonstrates a proven documented commitment to, and of having, implemented innovation more effectively within the non-invasive medical device field.

Furthermore, I strongly believe in, and as I believe my public works examples demonstrate, that I have contributed positively to the ethical implementation of technological innovations into the global healthcare arena. This is critical in my eyes, as the growing global tsunami in the costs associated with providing acceptable levels of healthcare that we are all faced with can only somewhat be averted by the intelligent allocation of existing resources and technology. The demographic changes are undeniable and unchangeable and with them the associated rise in people suffering from debilitating chronic diseases will not abate solely due to our lack of financial resources to deal with them. Without question improvements in prevention of these diseases and educating people on lifestyle changes to lessen their likelihood of developing them is paramount to the strategy. Even with this though, our societies as a whole will be faced with increasingly difficult decisions related to the rationing of healthcare. We must all do our part in reducing cost of care, be we in the policy making realm, industry, or healthcare provision arenas. More cost effective treatment modalities is one area where we can help, but clearly by moving care, where feasible, away from costly care sites such as hospitals and medical centres, is the most significant way to impact these cost moving forward, as only 70% of the costs are associated with manpower and infrastructure related items. I am most proud that my most significant contributions to the field detailed previously have all been associated with not just

clinical and patient quality of life improvements, but equally, in meaningfully contributing to reducing direct and ongoing healthcare costs related to the afflictions that they treat, this I believe is the essence of pragmatic entrepreneurship.

I would like to point out that I have found the entire process required to construct a coherent context statement rather exhausting at times but ultimately incredibly liberating. The level of reflection required to assess my claim has been intensive, not just as it relates to the public works materials themselves, but equally as it relates to myself and inner psyche. I feel like I have grown enormously because of the process, have honed my academic skills and feel even greater command of my professional abilities. I am passionate now to take these new entrepreneurial skills forward and continue to impact the community as positively as I can.

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